

Update date: February 1, 2024

## Group No. 5: Endocrinology and Metabolism

**RISEDRONIC ACID/ CHOLECALCIFEROL**

Clue	Description	Indications	Route of administration and dosage
010.000.6315.00	<p>TABLET</p> <p>Each tablet contains: Risedronate sodium 35.00 mg</p> <p>Vitamin D3 (cholecalciferol) 28.00 mg Equivalent to 2800 IU</p> <p>Package with 10 tablets.</p>	<p>Prophylaxis and treatment of Postmenopausal osteoporosis, with risk factors.</p> <p>Prophylaxis and treatment of corticosteroid-induced osteoporosis</p>	<p>Oral</p> <p>Adults and people over 18 years of age:</p> <p>35 mg/ 2800 IU every week (same day) on an empty stomach or 30 minutes before eating.</p>

## Generalities

Risedronate inhibits osteoclast-mediated bone resorption; It is a pyrivinyl bisphosphonate, which binds to bone hydroxyapatite. In this way, bone turnover is reduced, preserving the normal osteoblastic activity of the bone, as well as mineralization. Vitamin D deficiency is a risk factor for osteopenia and bone fractures. Serum values of 1.25 OHD < 15 ng/mL (37mM/L) progressively produce a decrease in bone mineralization, which can reach 80 to 90% in the most severe cases, and hypocalcemia that produces secondary hyperparathyroidism with an increase in bone resorption.

Calcium absorption is promoted by vitamin D and parathyroid hormone. Vitamin D is metabolized in the body resulting in 1, 25-dihydroxycholecalciferol, this is necessary for the active transport of calcium in the intestine, the excretion of calcium is carried out by the kidney. Parathyroid hormone stimulates calcium reabsorption at the kidney level.

## Risk in Pregnancy

c

## Adverse effects

General: pain, dyspepsia, nausea, abdominal pain, constipation, diarrhea, gastrointestinal disorders, musculoskeletal pain, headache, esophagitis, esophageal ulcer, gastritis, dysphagia, duodenitis, glossitis, esophageal stenosis. Iritis was observed as a very rare event in clinical studies.

## Contraindications and Precautions

## Contraindications

Hypersensitivity to the active ingredients or any of the excipients.

Hypocalcemia.

Pregnancy and lactation

Severe renal failure (creatinine clearance < 30 mL/minute).

Abnormalities in the esophagus (circumstances that delay esophageal emptying such as stricture or achalasia).

Inability to stand or sit upright for at least 30 minutes.

Calcium lithiasis, renal lithiasis, tissue calcification, for example, nephrocalcinosis.

Prolonged immobilization accompanied by hypercalciuria and/or hypercalcemia.

Precautions: foods, beverages (other than plain water) and drugs containing polyvalent cations

(such as calcium, magnesium, iron, and aluminum) may interfere with the absorption of risedronic acid/cholecalciferol should not be taken simultaneously.

Therefore, to obtain benefits from the risedronic acid/cholecalciferol combination, patients should take the tablet at least 30 minutes before the first meal or drink of the day, or at least two hours before or after eating food. or drinks at any other time of the day.

## Interactions

Concomitant ingestion of medications that contain polyvalent cations (for example: calcium, magnesium, iron and aluminum) interferes with the absorption of risedronate, so, if indicated, it should be taken at another time of day.

**BUROSUMAB**

Clue	Description	Indications	Route of administration and dosage
010.000.7017.00	<p>SOLUTION</p> <p>Each vial contains: burosomab 10 mg</p> <p>Container with a vial bottle with 1 mL (10 mg/mL)</p> <p>SOLUTION</p>	<p>Treatment of X-linked hypophosphatemia in children and adolescents aged 1 to 17 years with radiographic evidence of bone disease.</p>	<p>Subcutaneous Pediatric patients (1 to less than 18 years of age): Recommended starting dosage regimen of 0.8 mg/kg body weight, rounded to the nearest</p> <p>Nearest 10 mg given every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.</p> <p>Dose increase: Reassess level</p>

	Each vial contains: burosumab 20 mg		of fasting serum phosphorus every 4 weeks. If serum phosphorus is below the reference range for age, the dose may be increased in steps to approximately 2 mg/kg.  Dose reduction: If serum phosphorus is above the reference range for age, discontinue the next dose and reevaluate serum phosphorus level at  4 weeks. Once serum phosphorus is below the reference range for age, treatment can be restarted.
010.000.7017.01	Container with a vial with 1 mL (20 mg/mL)  SOLUTION Each vial contains: burosumab 30 mg		
010.000.7017.02	Container with a vial with 1 mL (30 mg/mL)		

#### Generalities

Immunoglobulin G subclass 1 (IgG1) antibody, anti-human fibroblast growth factor 23 (FGF23), produced by DNA recombination technology using Chinese hamster ovary cell.

#### Risk in Pregnancy

b

#### Adverse effects

Hypersensitivity, hyperphosphatemia, risk of nephrocalcinosis, injection site reactions.

#### Contraindications and Precautions

Hypersensitivity to the components of the formula, simultaneous administration with oral phosphate or active vitamin D analogues, do not initiate treatment with burosumab if serum phosphorus is between or above the normal range at age, severe deterioration of renal FUNCTION or end-stage renal disease because these conditions are associated with abnormal mineral metabolism.

#### Interactions

No drug interaction studies have been conducted with burosumab.

## BROMOCRIPTINE

Clue	Description	Indications	Route of administration and dosage
010.000.1096.00	TABLET  Each tablet contains: Bromocriptine mesylate equivalent to 2.5 mg of bromocriptine.  Package with 14 tablets.	Inhibition of lactation.  Hyperprolactinemia associated with amenorrhea and galactorrhea.  Acromegaly.  Parkinsonism.	Oral.  Adults:  1.25 to 2.5 mg/day. Fraction for every 8 hours.  Inhibition of lactation: 5 mg every 12 hours, for 14 days.

#### Generalities

It stimulates dopamine receptors, decreases dopamine turnover and inhibits the release of prolactin without affecting normal levels of other pituitary hormones. In patients with acromegaly it may reduce the elevated levels of growth hormone in patients with acromegaly.

#### Risk in Pregnancy

c

#### Adverse effects

Nausea, dizziness, vomiting, low blood pressure, headache, hallucinations, depression, nasal congestion and insomnia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to ergot derivatives, preeclampsia and Raynaud's syndrome.  
Precautions: Treatment with antihypertensives.

#### Interactions

Hormonal contraceptives, estrogens and progestins interfere with the effect of bromocriptine. The

Antidopaminergic medications decrease the effectiveness of bromocriptine. Antiparkinsonian drugs increase their pharmacological effect.

## GLIBENCLAMIDE

Clue	Description	Indications	Route of administration and dosage
010.000.1042.00	<p>TABLET</p> <p>Each tablet contains: Glibenclamide 5 mg.</p> <p>Package with 50 tablets.</p>	Diabetes mellitus type 2.	<p>Oral.</p> <p>Adults:</p> <p>2.5 to 5 mg every 24 hours, after food.</p> <p>Maximum dose 20 mg/day.</p> <p>Doses greater than 10 mg should be administered every 12 hours.</p>

### Generalities

Oral hypoglycemic agent derived from sulfonylureas that stimulates the activity of the beta cells of the pancreas, promoting the release of insulin.

### Risk in Pregnancy

C

### Adverse effects

Hypoglycemia, urticaria, fatigue, weakness, headache, nausea, diarrhea, reactive hepatitis, hemolytic anemia and spinal hypoplasia.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and sulfonamide derivatives. Type 1 diabetes mellitus, kidney failure, pregnancy and lactation.

### Interactions

Cyclophosphamide, oral anticoagulants, beta blockers and sulfonamides increase its hypoglycemic effect. Adrenergic corticosteroids, thiazide diuretics and furosemide decrease its hypoglycemic effect. A disulfiram-type reaction occurs with ethyl alcohol.

## GLIMEPIRID

Clue	Description	Indications	Route of administration and dosage
010.000.6337.01	<p>TABLETS</p> <p>Each tablet contains: Glimepiride 2 mg</p> <p>Container with 30 tablets</p>	Diabetes mellitus type 2	<p>Oral</p> <p>Adults</p> <p>The dosage is established according to the results of blood and urine glucose determinations.</p> <p>The initial dose is 1 mg once a day, if necessary, the daily dose can be increased, it is recommended that the increase be based on monitoring blood glucose levels and that the dose be increased gradually, for example at intervals. for one to two weeks and according to the following guidelines: 1 mg-2 mg-3 mg-4 mg-6 mg-8 mg glimepiride once a day.</p> <p>Dose interval in patients with well-controlled diabetes: The usual daily dose in patients with well-controlled diabetes is 1 to 4 mg of glimepiride.</p> <p>Doses of more than 6 mg daily are only effective in a minimal number of patients.</p>

### Generalities

It inhibits protein synthesis by binding to the 50 S ribosomal subunit.

### Risk in Pregnancy

C

### Adverse effects

Local irritation. Hypersensitivity. Superinfections with prolonged use.

Contraindications and Precautions
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Contraindications: Hypersensitivity to drugs, do not use in fungal or fungal eye conditions.  
Newly born.

Precautions: Do not use for more than 7 days.

Interactions
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None of clinical importance.

**HUMAN INSULIN**

Clue	Description	Indications	Route of administration and dosage
010.000.1050.00 010.000.1050.01	<p>INJECTABLE SUSPENSION NPH INTERMEDIATE ACTION</p> <p>Each mL contains: Isophane human insulin (DNA origin recombinant) 100 IU. — Human isophane zinc insulin (origin recombinant DNA) 100 IU.</p> <p>Container with a 5 mL vial. Container with a 10 mL vial.</p>	<p>Diabetes mellitus type 1.</p> <p>Acidosis and diabetic coma.</p> <p>Uncontrolled type 2 diabetes mellitus.</p> <p>Hyperkalemia.</p>	<p>Subcutaneous or intramuscular.</p> <p>Adults and children: The doses must be adjusted in each case and at the discretion of the specialist doctor.</p>
010.000.1051.00 010.000.1051.01	<p>REGULAR FAST ACTING INJECTABLE SOLUTION</p> <p>Each mL contains: Human insulin (DNA origin recombinant) 100 IU. — Human isophane zinc insulin (origin recombinant DNA) 100 IU.</p> <p>Container with a 5 mL vial. Container with a 10 mL vial.</p>		<p>Subcutaneous, intramuscular or intravenous.</p> <p>Adults and children: The doses must be adjusted in each case and at the discretion of the specialist doctor.</p>
010.000.4157.00	<p>INJECTABLE SUSPENSION SLOW INTERMEDIATE ACTION</p> <p>Each mL contains: Human compound zinc insulin (recombinant DNA origin) 100 IU.</p> <p>Container with a 10 mL vial.</p>		<p>Subcutaneous or intramuscular.</p> <p>Adults: The doses must be adjusted in each case and at the discretion of the specialist doctor.</p>

Generalities
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Hormone that increases glucose transport across the membrane and influences the activity of various enzymes of intermediate metabolism.

Risk in Pregnancy
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Adverse effects
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Immediate hypersensitivity. Hypoglycemic syndrome. Lipodystrophy.

Contraindications and Precautions
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Contraindications: Hypersensitivity to the drug.

Interactions
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Alcohol, beta blockers, salicylates, monoamine oxidase inhibitors and tetracyclines increase the hypoglycemic effect.  
Corticosteroids, thiazide diuretics and furosemide reduce the hypoglycemic effect.

**METFORMIN**

Clue	Description	Indications	Route of administration and dosage
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010.000.5165.00	<p>TABLET</p> <p>Each tablet contains: Metformin hydrochloride 850 mg.</p> <p>Package with 30 tablets.</p>	Diabetes mellitus type 2.	<p>Oral.</p> <p>Adults:</p> <p>850 mg every 12 hours with food. Maximum dose 2550 mg per day.</p>
010.000.6275.00	<p>Each tablet contains: Metformin hydrochloride extended release 500 mg.</p> <p>Package with 30 tablets.</p>		<p>Extended release 500 or 750 mg each 24 hours. The dose should not be exceeded 2000 mg per day.</p>

#### Generalities

Biguanide that increases the peripheral effect of insulin and decreases gluconeogenesis.

#### Risk in Pregnancy

d

#### Adverse effects

Gastrointestinal intolerance, headache, transient skin allergies, metallic taste and lactic acidosis.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, type 1 diabetes mellitus, diabetic ketoacidosis, kidney failure, liver failure, heart or lung failure, severe malnutrition, chronic alcoholism and acute alcohol poisoning. Pregnancy and lactation.

#### Interactions

Decreases the absorption of vitamin B12 and folic acid. Sulfonylureas promote the hypoglycemic effect. Cimetidine increases the plasma concentration of metformin.

## PREDNISONE

Clue	Description	Indications	Route of administration and dosage
010.000.0472.00	<p>TABLET</p> <p>Each tablet contains: Prednisone 5 mg.</p> <p>Package with 20 tablets.</p>	<p>Addison's disease.</p> <p>Immunoallergic or inflammatory diseases.</p> <p>Nephrotic syndrome.</p>	<p>Oral.</p> <p>Adults:</p> <p>From 5 to 60 mg/day, single or divided dose every 8 hours. The maintenance dose is established according to the therapeutic response; and subsequently it is gradually decreased until the minimum effective dose is reached.</p> <p>Maximum dose: 250 mg/day.</p> <p>Children:</p> <p>0.5 to 2 mg/kg body weight/day or 25 to 60 mg/m<sup>2</sup> of body surface, divided every 6 to 12 hours.</p>
010.000.0473.00	<p>TABLET</p> <p>Each tablet contains: Prednisone 50 mg.</p> <p>Package with 20 tablets.</p>		

#### Generalities

Intermediate-acting glucocorticoid that induces RNA transcription, promoting the synthesis of enzymes responsible for its effects.

#### Risk in Pregnancy

b

#### Adverse effects

Posterior subcapsular cataract, adrenal hypoplasia, Cushing's syndrome, obesity, osteoporosis, gastritis, superinfections, glaucoma, hyperosmolar coma, hyperglycemia, muscle hypercatabolism, delayed healing and growth retardation.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and systemic mycosis.  
Precautions: Peptic ulcer, systemic arterial hypertension, diabetes mellitus, liver and kidney failure and immunosuppression.

#### Interactions

With digitalis the risk of cardiac arrhythmias and digitalis poisoning increases. Increases the biotransformation of isoniazid. Hypokalemia increases with thiazide diuretics, furosemide and amphotericin B. Rifampicin, phenytoin and phenobarbital increase its hepatic biotransformation. With estrogen its biotransformation decreases. With antacids, its intestinal absorption decreases. Paracetamol increases the hepatotoxic metabolite.

## ACARBOSE

Clue	Description	Indications	Route of administration and dosage
010.000.5166.00	<p>TABLET</p> <p>Each tablet contains: Acarbose 50 mg.</p> <p>Package with 30 tablets.</p>	Diabetes mellitus type 2.	<p>Oral.</p> <p>Adults:</p> <p>50 to 100 mg every 8 hours, at the beginning of the three main meals.</p> <p>Maximum dose 600 mg per day.</p>

### Generalities

Oligosaccharide of microbial origin that reduces postprandial glycemia, by reversible and competitive inhibition of pancreatic alpha amylase and alpha-glucosidohydrolase, at the level of the intestinal villi, which slows the passage of carbohydrates to the plasma.

### Risk in Pregnancy

b

### Adverse effects

Flatulence, borborygmi, abdominal pain, diarrhea, allergic reactions, hypoglycemia and absorption syndrome poor intestinal.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Patients with ketoacidosis, malabsorption syndrome and ulcerative colitis.

Precautions: During breastfeeding, severe renal failure and children under 18 years of age.

### Interactions

Intestinal adsorbents reduce the effect of acarbose. Insulin, metformin, and sulfonylureas increase the risk of hypoglycemia.

## CARGLUMIC ACID

Clue	Description	Indications	Route of administration and dosage
010.000.6151.01	<p>TABLET</p> <p>Each tablet contains: Carglumic acid 200 mg</p> <p>Package with 60 tablets.</p>	<p>Treatment of hyperammonemia due to:</p> <p>N-acetylglutamate deficiency synthetase (NAGS) Acidemia Isovaleric (IVA) Acidemia Methylmalonic (MMA) Acidemia propionic (PA)</p>	<p>Oral.</p> <p>For glutamatosynthetase deficiency: N-acetyl</p> <p>Based on clinical experience, treatment can begin from the first day of life. Initial dose should be 100 mg/kg up to 250 mg/kg if necessary.</p> <p>It must subsequently be adjusted individually in order to maintain plasma levels of normal ammonia. In the long term, it may not be necessary to increase the dose based on body weight as long as adequate metabolic control is achieved; daily doses range from 10 mg/kg to 100 mg/kg.</p> <p>Carglumic acid response test. It is recommended to check the individual response to carglumic acid before starting long-term treatment. For example: In a child in a coma, start with a dose of between 100 to 250 mg/kg/day and measure the plasma ammonia concentration at least before each administration; It should normalize a few hours after starting treatment with carglumic acid.</p> <p>In a patient with moderate hyperammonemia, administer a test dose of between 100 and</p>

200 mg/kg/day for 3 days with constant protein administration and repeatedly determine plasma ammonia concentration (before and 1 hour after food); Adjust the dose to maintain normal plasma ammonia levels.

For isovaleric acidemia, methylmalonic acidemia, and propionic acidemia:  
Treatment should begin after hyperammonemia in patients with organic acidemia. The initial daily dose should be 100 mg/kg, reaching up to 250 mg/kg if necessary. It must then be individually adjusted to maintain normal plasma ammonia levels.

Methods of Administration: Based on pharmacokinetic data and clinical experience, it is recommended to divide the total daily dose between two and four doses to be administered before meals. Splitting the tablets in half allows the dosage to be adjusted as necessary.

Occasionally it can be divided into quarters of tablets to adjust the dosage prescribed by the doctor.

The tablets can be dissolved in a minimum of 5-10 mL of water and swallowed immediately.

#### Generalities

Carglumic acid is a structural analogue of N-acetyl glutamate, which is the natural activator of carbamylphosphate synthetase, the first enzyme of the urea cycle. Carglumic acid has been shown to activate hepatic carbamylphosphate synthetase. Although the affinity of carbamylphosphate synthetase for carglumic acid is lower than for N-acetyl glutamate, carglumic acid has been shown to stimulate carbamoylphosphate synthetase and to be much more effective than N-acetyl glutamate as a protector against ammonia poisoning

#### Risk in Pregnancy

d

#### Adverse effects

Increased sweating, increased aminotransferases, bradycardia, diarrhea, vomiting, pyrexia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

#### Interactions

No specific interaction studies have been performed

## AGALSIDASE ALPHA

Clue	Description	Indications	Route of administration and dosage
010.000.5549.00	<p>INJECTABLE SOLUTION</p> <p>Each vial contains: Agalsidase alfa 3.5 mg.</p> <p>Container with vial bottle with 3.5 mL (1 mg/mL).</p>	Fabry disease.	<p>Intravenous infusion.</p> <p>Children and adolescents between 7 and 18 years of age, adults:</p> <p>0.2 mg/kg body weight, every two weeks.</p>

#### Generalities

Agalsidase alfa catalyzes the hydrolysis of globotriaosylceramide (Gb3 or CTH), which cleaves a terminal galactose residue from the molecule.

#### Risk in Pregnancy

x

#### Adverse effects

Peripheral edema, headache, dizziness, dysgeusia, neuropathic pain, tremors, hypersomnia, hypoesthesias, paresthesias, increased lacrimation, tachycardia, palpitations, hypertension, nausea, diarrhea, vomiting, abdominal pain, acne, erythema, pruritus, rash, livedo reticularis, musculoskeletal discomfort, myalgia, low back pain, pain in the extremities, peripheral swelling, arthralgia, joint swelling. Development of IgG antibodies to the protein.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and breastfeeding.

Precautions: The most common symptoms related to infusion are chills, headache, nausea, pyrexia, flushing, tachycardia, urticaria, angioneurotic edema with a sensation of oppression, stridor, swelling of the tongue, dizziness and hyperhidrosis.

### Interactions

Agalsidase alfa should not be administered concomitantly with chloroquine, amiodarone, benoquine or gentamicin, since these substances may inhibit the intracellular activity of  $\beta$ -galactosidase.

## AGALSIDASE BETA

Clue	Description	Indications	Route of administration and dosage
010.000.5546.00	<p>INJECTABLE SOLUTION</p> <p>Each vial with powder or lyophilisate contains: Agalsidase beta 35 mg.</p> <p>Container with vial bottle with lyophilized powder.</p>	Fabry disease enzyme deficiency Alpha Galactosidase A.	<p>Intravenous infusion.</p> <p>Children, adolescents and adults: 1 mg/kg body weight, once every two weeks.</p> <p>Administer diluted in 0.9% sodium chloride intravenous solutions, packaged in glass bottles (reconstituted patient dose in 500 mL).</p>
010 .000.6116.00	<p>INJECTABLE SOLUTION</p> <p>Each vial with lyophilized powder contains: Agalsidase beta 5 mg</p> <p>Container with vial bottle with lyophilized powder</p>		<p>The initial infusion rate should not be greater than .25 mg/min (15 mg/hour).</p> <p>The total infusion period should not be less than 2 hours.</p>

### Generalities

Enzyme analogue of human Acid Alpha Galactosidase, purified by means of recombinant DNA technology, using live cell cultures from Chinese hamster ovary. Agalsidase Beta acts on the underlying cause of Fabry disease due to the deficiency, lack or malfunction of the enzyme Alpha Acid Galactosidase which causes an abnormal accumulation of GL3 (globotriosylceramide) in the vascular endothelial cells.

### Risk in Pregnancy

c

### Adverse effects

Nausea, vomiting, headache, paresthesia, flushing, chills, pyrexia, feeling of cold, tachycardia, bradycardia, palpitations, lacrimation, tinnitus, vertigo, dyspnea, nasal congestion, throat tightness, nasopharyngitis, wheezing cough, pruritus, erythema, urticaria, facial swelling, extremity pain, myalgia, arthralgia and lower back pain.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Patients with antibodies to agalsidase beta (rh $\beta$ GAL) are more likely to experience drug infusion-associated reactions, defined as any adverse reaction that occurs on the day of administration. These patients should be treated with caution with subsequent administration of agalsidase beta. Antibody status against agalsidase beta should be monitored regularly.

### Interactions

Do not administer Agalsidase beta with chloroquine, amiodarone, benoquine or gentamicin, due to the risk of inhibition of intracellular  $\beta$ -galactosidase activity.

## ALPHA ALGLUCOSIDASE

Clue	Description	Indications	Route of administration and dosage
	<p>INJECTABLE SOLUTION</p> <p>Each vial with powder contains: Alglucosidase alfa 50 mg.</p>	Pompe disease due to deficiency of Alpha Glucosidase enzyme acidic	<p>Intravenous infusion.</p> <p>Children, adolescents and adults. 20 mg/kg body weight, once every 2 weeks.</p>



010.000.5548.00 Container with vial with lyophilized powder.

Administer diluted in 0.9% sodium chloride intravenous solutions, packaged in glass bottles (reconstituted dose dilute obtain to concentration of 0.5 mg/mL to 4 mg/mL).

Initial rate of 1 mg/kg body weight/hour, gradually increase by 2 mg/kg body weight/hour every 30 minutes if no signs of infusion-associated reactions occur up to a maximum of 7 mg/kg body weight body/hour.

#### Generalities

Analog of the human Acid Alpha Glucosidase enzyme, purified by recombinant DNA technology using live Chinese hamster ovary cell cultures. Alglucosidase Alfa acts on the underlying cause of Pompe disease, due to the deficiency, lack or malfunction of the enzyme Alpha Acid Glucosidase, indicated in the treatment of patients with Pompe disease in its early and late varieties.

#### Risk in Pregnancy

c

#### Adverse effects

Vomiting, urticaria, erythema, maculopapular rash, facial redness, hypertension, pallor, agitation, tremor, tachycardia, cyanosis, cough, tachypnea, pyrexia and chills.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Anaphylactic reactions, infusion-associated reactions and patients with an advanced stage of Pompe disease.

#### Interactions

No drug interaction studies have been performed with alglucosidase alfa. As it is a human recombinant protein, cytochrome P450-mediated drug interactions are unlikely to occur with alglucosidase alfa.

## ALIROCUMAB

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION Each prefilled pen or prefilled syringe contains:  Alirocumab 75 mg	Treatment of the hypercholesterolemia (heterozygous familial and non-familial) in patients at very high cardiovascular risk who do not achieve LDL-C goals, in addition to the maximum tolerated dose of statins and/or ezetimibe.	Subcutaneous.  Adults: 75 mg once every 2 weeks. For patients requiring greater LDL-C reduction (>60%) may start with 150 mg once every 2 weeks
010.000.6087.01	Package with 2 pens prefilled with 1 mL of solution (75 mg/mL).		
010.000.6087.02	Package with 6 pens prefilled with 1 mL of solution (75 mg/mL).		
010.000.6087.03	Package with 1 syringe prefilled with 1 mL of solution (75 mg/mL).		
010.000.6087.04	Package with 2 syringes prefilled with 1 mL of solution (75 mg/mL).		
010.000.6087.05	Package with 6 syringes prefilled with 1 mL of solution (75 mg/mL).		
	INJECTABLE SOLUTION Each prefilled pen or prefilled syringe contains:  Alirocumab 150 mg		
010.000.6088.01	Package with 2 pens prefilled with 1 mL of solution (150 mg/mL).		
010.000.6088.02	Package with 6 pre-filled pens		

010.000.6088.03	with 1 mL of solution (150 mg/mL).		
010.000.6088.04	Package with 1 syringe prefilled with 1 mL of solution (150 mg/mL).		
010.000.6088.05	Package with 2 syringes prefilled with 1 mL of solution (150 mg/mL).		
010.000.6088.05	Package with 6 syringes prefilled with 1 mL of solution (150 mg/mL).		

#### Generalities

Alirocumab is a fully human IgG1 monoclonal antibody that binds with high affinity and specificity to the proprotein convertase subtilisin kexin type 9 (PCSK9). By inhibiting the binding of PCSK9 to LDLR, alirocumab increases the number of LDLR available to remove LDL, thereby reducing LDL-C levels.

#### Risk in Pregnancy

b

#### Adverse effects

Local reactions at the injection site, signs and symptoms in the upper respiratory tract and pruritus. Hypersensitivity, nummular eczema, urticaria and hypersensitivity vasculitis.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug

Precautions: It should be used with caution in patients with severe renal and hepatic insufficiency.

#### Interactions

Alirocumab is a biological drug, so no pharmacokinetic effects are anticipated with other medications or on cytochrome P450 enzymes. Regarding the effects of other medications on alirocumab, it is known that statins and other lipid-lowering therapies increase the production of PCSK9, the target protein of alirocumab.

## ATORVASTATIN

Clue	Description	Indications	Route of administration and dosage
	TABLET	Hypercholesterolemia.	Oral.
	Each tablet contains: Atorvastatin calcium trihydrate equivalent to 20 mg of atorvastatin.	Hyperlipidemias.	Adults:
010.000.5106.00	Package with 10 tablets.		20 mg every 24 hours, increase the dose according to response.
010.000.5106.01	Package with 30 tablets.		Maximum dose 80 mg/day.

#### Generalities

It reduces plasma concentrations of cholesterol and lipoproteins, competitively inhibiting HMG-CoA reductase in the liver and increasing the number of hepatic receptors for LDL on the cell surface. Reduces LDL production.

#### Risk in Pregnancy

x

#### Adverse effects

Constipation, flatulence, dyspepsia, abdominal pain, headache, myalgia, asthenia and insomnia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, pregnancy and lactation, and active liver disease.

#### Interactions

Antacids reduce the plasma concentrations of atorvastatin and erythromycin increases them. Atorvastatin increases plasma concentrations of digoxin. Fibrates increase the risk of myopathy.

## BEZAFIBRATE

Clue	Description	Indications	Route of administration and dosage
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010.000.0655.00	TABLET	Hyperlipidemias.	Oral.
	Each tablet contains: Bezafibrate 200 mg.		Adults: 200 to 300 mg every 12 hours, after food.
	Package with 30 tablets.		Children: 5 to 10 mg/kg body weight/day, divided dose every 8 hours.

#### Generalities

Hypolipidemic agent that decreases hepatic lipoprotein synthesis by blocking lipolysis of adipose tissue and reducing the concentration of free fatty acids. Increases plasma clearance of low-density cholesterol.

#### Risk in Pregnancy

x

#### Adverse effects

Nausea, vomiting, bloating, diarrhea, weight gain, headache and insomnia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, liver or kidney failure and cholecystopathy.

#### Interactions

Increases the effect of oral anticoagulants. Increases the effect of insulin and oral hypoglycemic agents.

### CALCIUM

Clue	Description	Indications	Route of administration and dosage
010.000.1006.00	EFFERVESCENT TABLET	Hypocalcemia.	Oral.
	Each tablet contains: Calcium gluconate lactate 2.94 g. Calcium carbonate 300 mg. equivalent to 500 mg of ionizable calcium.		Adults: 500 to 1000 mg every 12 hours.
	Package with 12 tablets.		Children: 250 to 500 mg every 12 hours.  The tablets must be dissolved in 200 mL of water.

#### Generalities

Essential electrolyte that participates in the normal function of muscle and nerve cells and in blood coagulation mechanisms. It also intervenes in the ossification of the bone matrix.

#### Risk in Pregnancy

c

#### Adverse effects

Gastrointestinal disorders, hypercalcemia, nausea, constipation and thirst.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, hypercalcemia, renal failure, hypercalciuria and kidney stones

#### Interactions

Tetracyclines and corticosteroids decrease intestinal absorption. Decreases the therapeutic effect of calcium blockers. Increases the risk of digitalis toxicity.

### CALCITONIN

Clue	Description	Indications	Route of administration and dosage
010.000.5161.00	INJECTABLE SOLUTION	Osteoporosis.  Hypercalcemia.  Paget's disease.	Intramuscular, subcutaneous or intravenous infusion.
	Each vial or vial with solution or lyophilisate contains: Synthetic salmon calcitonin 50 IU.		Adults:  Intramuscular and subcutaneous: 50 to 100 IU every 24 hours or alternate days.
	Container with 5 ampoules or vial bottles with diluent.		Intravenous infusion: 5 to 10 IU/kg body weight/day.
010.000.5161.01	Container with 6 ampoules or vial bottles with diluent.		
010.000.5161.02	Container with 12 ampoules or vial bottles with diluent.		Administer diluted in intravenous solutions packaged in bottles of

			glass.
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#### Generalities

Hypocalcemic hormone, whose effects generally oppose those of parathyroid hormone, which produces direct inhibition of osteoclastic bone resorption.

#### Risk in Pregnancy

C

#### Adverse effects

Vertigo, nausea, vomiting, chills, hyporexia and weight loss. Erythema at the injection site. Swelling of the hands.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Keep refrigerated at a temperature between 2 and 8 °C. Use immediately as it does not contain conservatives.

#### Interactions

None of clinical importance.

## CALCITRIOL

Clue	Description	Indications	Route of administration and dosage
010.000.1095.00	SOFT GELATIN CAPSULE  Each capsule contains: Calcitriol 0.25 µg.  Container with 50 capsules.	Hypoparathyroidism.  Renal osteodystrophy.	Oral.  Adults:  Initial 0.25 µg/day. Increase the dose over two to four weeks at intervals of 0.5 to 3 µg/day.  Children:  Initial: 0.25 µg/day. Increase the dose by 2 to 4 weeks at 0.25 to 2 intervals µg/day.

#### Generalities

Most active form of vitamin D. In the body it is synthesized from cholecalciferol.

#### Risk in Pregnancy

C

#### Adverse effects

Nausea, vomiting and hypercalcemia, which leads to generalized vascular calcification.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug or vitamin D and hypercalcemia.

Precautions: Patients using digitalis.

#### Interactions

Antagonizes the therapeutic effect of calcium blockers. With thiazides the risk of hypercalcemia increases.

## CALCIUM CARBONATE / VITAMIN D3

Clue	Description	Indications	Route of administration and dosage
010.000.6000.00	TABLET Each tablet contains: Calcium carbonate 1666,670 mg equivalent to 600 mg of calcium Cholecalciferol 6.2 mg equivalent to 400 IU  of Vitamin D3  Container with 30 tablets	Adjuvant in treatment of osteoporosis.	Oral.  Adults:  1 tablet twice a day with food.

#### Generalities

Calcium is one of the essential minerals in the bone structure and 99% of the calcium that the human body has.

It is found in the skeleton. For years there has been evidence that adequate calcium intake in the early stages of life prevents subsequent loss of bone mass in later stages.

Vitamin D is formed in the skin by exposure to ultraviolet rays, and plays an important role in the absorption of calcium, bone health, muscle performance, balance and risk of falls. It is responsible for regulating adequate levels of serum calcium and promoting proper intestinal absorption of the mineral.

**Risk in Pregnancy**

TO

**Adverse effects**

Abdominal distension or pain, constipation, diarrhea, belching, flatulence, nausea, vomiting. Hypercalciuria, nephrolithiasis.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug.

Precautions: No studies have been conducted during pregnancy in humans, but no undesirable effects have been reported at therapeutic doses.

**Interactions**

Calcium may reduce the oral absorption of antibiotics such as fluoroquinolones, tetracyclines, or levothyroxine or phenytoin. Calcium can reduce the response to calcium channel blockers and in high doses increases the risk of cardiac arrhythmias in digitalized patients. Intestinal calcium uptake can be decreased by the simultaneous intake of some foods such as spinach, rhubarb, bran, other cereals, milk and dairy products. Concomitant administration with estrogens may increase calcium absorption. It should not be administered with antacids containing magnesium.

**CINACALCET**

Clue	Description	Indications	Route of administration and dosage
010.000.5835.00	<p>TABLET</p> <p>Each tablet contains: Cinacalcet 30 mg.</p> <p>Package with 30 tablets.</p>	<p>Hyperparathyroidism secondary in patients with Chronic Kidney Failure on dialysis who are refractory to conventional therapy with parathyroid hormone levels greater than 85 pmol/L or</p>	<p>Oral.</p> <p>Adults:</p> <p>For Secondary Hyperparathyroidism: initial dose of 30 mg daily with titration every 2 to 4 weeks to a maximum of 180 mg per day. With food or shortly after eating. The tablets should be taken whole and not divided.</p>
010.000.7124.00	<p>TABLET</p> <p>Each tablet contains: Cinacalcet 60 mg.</p> <p>Package with 30 tablets.</p>	<p>800 pg/mL, in whom parathyroidectomy is contraindicated.</p>	

**Generalities**

Calcimimetic agent, allosteric modulator of the calcium sensing receptor in the parathyroid gland, which increases sensitivity to calcium and reduces the secretion of parathyroid hormone and simultaneously decreases calcium, phosphorus and the calcium- phosphorus product.

**Risk in Pregnancy**

C

**Adverse effects**

Nausea and vomiting.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug.

Precautions: Monitor serum calcium levels for symptoms of hypocalcemia.

**Interactions**

CYP3A4 enzyme inhibitors, and medications metabolized by CYP2D6.

**CYSTEAMINE**

Clue	Description	Indications	Route of administration and dosage
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010.000.6125.00	<b>CAPSULE</b>  Each capsule contains: Cysteamine bitartrate equivalent to 150 mg of cysteamine  Container with 100 capsules	Treatment of confirmed nephropathic cystinosis.	Oral.  Children up to 12 years: 1.30 g/m <sup>2</sup> /day, divided into 4 doses per day.  Patients over 12 years of age and weighing over 50 kg:  2 g/day, divided into 4 doses per day.
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#### Generalities

Cysteamine is a product of the alimentary tract and metabolism, code ATC.A16AA04.6. Normal individuals and people heterozygous for cystinosis have leukocyte cystine levels < 0.2 and usually less than 1 nmol hemicystin/mg of protein, respectively. Individuals with nephropathic cystinosis present an elevation of leukocyte cystine above 2 nmol hemicystine protein. Cysteamine reacts with cystine giving rise to a mixture of cysteamine disulphide and cysteine, in addition to cysteine. The disulphide mixture is then removed from lysosomes by an intact lysine transporter system. The decrease in leukocyte cystine levels correlates with the plasma cysteamine concentration during the six hours following

Cysteamine administration

#### Risk in Pregnancy

X

#### Adverse effects

Abnormalities in liver function tests, Leukopenia, Headache, encephalopathy, drowsiness, seizures, vomiting, nausea, diarrhea, abdominal pain, bad breath, dyspepsia, gastroenteritis, gastrointestinal ulcer, nephrotic syndrome, hair color change, anorexia, asthenia, unpleasant skin odor, rash, lethargy, fever

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the Drug. Patients who have presented hypersensitivity to penicillamine.  
 Precautions: For maximum benefit, Cysteamine therapy should be initiated promptly upon confirmation of the diagnosis of nephropathic cystinosis. Nephropathic cystinosis must have been diagnosed through clinical examinations such as biochemical evaluations (leukocyte cystine level measurements).

#### Interactions

It can be used together with electrolyte and mineral supplements necessary in the treatment of Falconi syndrome, as well as vitamin D and thyroid hormones. Indomethacin has been administered concomitantly with Cysteamine in certain patients. Patients undergoing kidney transplantation have used treatments to prevent rejection along with cysteamine.

## DAPAGLIFLOZIN

Clue	Description	Indications	Route of administration and dosage
010.000.6007.00	<b>TABLET</b>  Each tablet contains: Dapagliflozin propanediol equivalent to 10 mg of dapagliflozin  Package with 14 tablets.	Diabetes treatment mellitus type 2 when metformin therapy does not provide adequate glycemic control.  Treatment of heart failure with reduced ejection fraction.	Oral.  Adults: 10 mg every 24 hours Take in combination with metformin.
010.000.6007.01	Package with 28 tablets.	Treatment of chronic kidney disease with glomerular filtration rate of 25 to 75 mL/min/1.73 m <sup>2</sup> with and without diabetes	

#### Generalities

Dapagliflozin is the first sodium-glucose co-transporter 2 (SGLT2) inhibitor approved in Mexico, it is characterized by being highly selective and reversible, it represents the first drug in its class due to its mechanism of action. SGLT2 is selectively expressed in segment 1 of the proximal convoluted tubule of the kidney and is responsible for reabsorbing 90% of filtered glucose. Dapagliflozin improves fasting and postprandial plasma glucose concentrations by reducing renal glucose reabsorption, resulting in urinary excretion of glucose (glycosuria).

## Risk in Pregnancy

c

## Adverse effects

Genital and urinary infections. The frequency of hypoglycemia depends on the type of concomitant therapy (insulin or sulfonylurea).

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: In patients at risk of hypoglycemia and on insulin and/or sulfonylurea therapy. The efficacy of Dapagliflozin depends on renal function, it should not be used in patients with moderate to severe renal impairment (defined as eGFR <45 mL/min/1.73m<sup>2</sup> by MRHD or CrCl <60 mL/min by Cockcroft-Gault), not for safety reasons but for a decrease in effectiveness.

## Interactions

The metabolism of dapagliflozin is primarily mediated by UGT1A9-dependent glucuronide conjugation.

In studies in healthy subjects, the pharmacokinetics of dapagliflozin were not altered by metformin, pioglitazone (a [major] substrate of CYP2C8 and [secondary] of CYP3A4), sitagliptin (a substrate of hOAT-3 and P-glycoprotein), glimepiride, voglibose, hydrochlorothiazide, bumetanide, valsartan or simvastatin. A 22% decrease in systemic exposure of dapagliflozin following coadministration with rifampicin was considered not large enough to justify a dose adjustment.

**DEFLAZACORT**

Clue	Description	Indications	Route of administration and dosage
010.000.4505.00	<p>TABLET</p> <p>Each tablet contains: Deflazacort 6 mg.</p> <p>Package with 20 tablets.</p>	<p>Inflammatory processes severe and autoimmune.</p>	<p>Oral.</p> <p>Adults:</p> <p>Initial: 6-120 mg per day, depending on the severity of the clinical condition.</p> <p>Support: 18 mg per day, which should be adjusted according to clinical response.</p> <p>Children:</p> <p>0.25-2 mg per day, although it will depend on the severity of the clinical condition and should be adjusted according to the clinical response.</p>
010.000.4507.00	<p>TABLET</p> <p>Each tablet contains: Deflazacort 30 mg.</p> <p>Package with 10 tablets.</p>		
010.000.4509.00	<p>SUSPENSION</p> <p>Each mL of suspension contains: Deflazacort 22.75 mg.</p> <p>Container with glass bottle with 13 mL of suspension and dropper.</p>		

## Generalities

Oxazoline derivative of the glucocorticoid prednisolone, with immunomodulatory and anti-inflammatory properties.

## Risk in Pregnancy

b

## Adverse effects

Systemic gastrointestinal, metabolic and nutritional, central and peripheral nervous system, psychiatric and skin disorders.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

## Interactions

With cardiac glycosides or diuretics, the risk of hypokalemia increases.

**DENOSUMAB**

Clue	Description	Indications	Route of administration and dosage
	<p>INJECTABLE SOLUTION</p> <p>Each prefilled syringe contains:</p>	<p>Intolerant postmenopausal women</p>	<p>Subcutaneous.</p> <p>Adults:</p>

010.000.5613.00	Denosumab 60 mg. Package with a prefilled syringe with 1 mL.	oral bisphosphonates, with previous fracture and high risk of fracture.	60 mg once every six months.
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#### Generalities

Denosumab is a human monoclonal antibody (IgG2) that targets and binds with high affinity and specificity to RANKL, preventing the activation of its receptor, RANK, on the surface of osteoclast precursors and in osteoclasts. Preventing the RANKL/RANK interaction inhibits the formation, function, and survival of osteoclasts, which in turn causes decreased bone resorption in trabecular and cortical bone.

#### Risk in Pregnancy

c

#### Adverse effects

Urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, rash, pain in extremities.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Hypocalcemia. Patients receiving Denosumab may develop skin infections (mainly cellulitis) requiring hospitalization.

#### Interactions

No interaction studies have been performed.

## DESMOPRESSIN

Clue	Description	Indications	Route of administration and dosage
010.000.5690.00	TABLET Each tablet contains: Desmopressin acetate equivalent to 60 µg of desmopressin. Package with 30 tablets.	Nocturnal enuresis.	Oral.  Children from 6 to 12 years of age: Initial dose: 120 µg at bedtime, sublingually, every 24 hours.  If necessary, the dose can be increased to 240 µg. It should be accompanied by nocturnal fluid restriction.
010.000.5691.00	TABLET Each tablet contains: Desmopressin acetate equivalent to 120 µg of desmopressin. Package with 30 tablets.		
010.000.1099.00	TABLET Each tablet contains: Desmopressin acetate 0.2 mg equivalent to 178 µg of desmopressin. Package with 30 tablets.	Diabetes insipidus.  Primary enuresis.	Oral.  Adults and children:  100 to 200 µg of desmopressin acetate every 24 hours, before bedtime.
010.000.1097.00	NASAL SOLUTION Each mL contains: Desmopressin acetate equivalent to 89 µg of desmopressin. Nebulizer container with 2.5 mL.		Intranasal.  Adults: From 5 to 40 µg/day, every 8 hours.  Children from 3 months to 12 years: 5 to 30 µg daily in one dose.
010.000.5169.00	INJECTABLE SOLUTION Each vial contains: Desmopressin Acetate 15 µg. Container with 5 vials with one mL.		Intravenous.  Adults: 0.3 µg body weight. It can be repeated after 6 hours.

#### Generalities

Vasopressin analogue that increases the permeability of the convoluted tubules and promotes water reabsorption, producing an increase in urine osmolarity and a decrease in urine volume. Increases the von factor



Willebrand and shortens the bleeding time.

Risk in Pregnancy

b

Adverse effects

Abdominal pain, nausea, facial flushing during administration, paleness and headache.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, von Willebrand disease type IIB, coronary heart disease, high blood pressure, hemophilia and nasal congestion.

Interactions

Carbamazepine, chlorpropamide and non-steroidal anti-inflammatory drugs increase their antidiuretic effect.

## DEXAMETHASONE

Clue	Description	Indications	Route of administration and dosage
010.000.3432.00	<p>TABLET</p> <p>Each tablet contains Dexamethasone 0.5 mg.</p> <p>Package with 30 tablets.</p>	<p>Allergic diseases.</p> <p>Inflammatory diseases.</p> <p>Addison's disease.</p> <p>Bronchial asthma.</p>	<p>Oral.</p> <p>Adults:</p> <p>Initial: 0.25 to 4 mg/day, divided every 8 hours.</p> <p>Maintenance: 0.5 to 1.5 mg/day, divided every 8 hours. The dose should be reduced gradually until the desired therapeutic effect is achieved.</p> <p>Children:</p> <p>0.2 to 0.3 mg/kg body weight/day, divided every 8 hours.</p>

Generalities

Glucocorticoid that inhibits phospholipase A2 and therefore inhibits the synthesis of proteins, thromboxanes and leukotrienes.

Risk in Pregnancy

c

Adverse effects

Cataract, Cushing's syndrome, obesity, osteoporosis, gastritis, superinfections, glaucoma, hyperglycemia, muscle hypercatabolism, delayed healing and growth retardation

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Systemic mycosis. Precautions: Peptic ulcer, high blood pressure, DM 1 and DM 2, liver and kidney failure, immunosuppression, therapy with thiazides and furosemide.

Interactions

Alcohol and non-steroidal anti-inflammatory drugs increase gastrointestinal adverse effects. Ephedrine, phenobarbital and rifampin decrease the therapeutic effect.

## ELOSULPHASE ALPHA

Clue	Description	Indications	Route of administration and dosage
010.000.6073.00	<p>INJECTABLE SOLUTION</p> <p>Each vial contains: Elosulfase alfa 5 mg</p> <p>Package with a vial with 5 mL (5 mg/5 mL).</p>	<p>Treatment of mucopolysaccharidosis IV type A (Morquio A syndrome, MPS IV-A).</p>	<p>Intravenous.</p> <p>Children and adults:</p> <p>2 mg per kg of body weight administered once a week as an intravenous infusion over a minimum period of 3.5 to 4.5 hours, based on the volume of the infusion.</p>

Generalities

Elosulfase Alfa is a purified human enzyme, produced by recombinant DNA technology in a Chinese hamster ovarian cell line. Human N-acetylgalactosamine-6-sulfatase is a glycosaminoglycan-specific lysosomal hydrolytic enzyme that hydrolyzes galactose sulfate-6-sulfate or N-acetyl-galactosamine-6-sulfate in the

non-reducing ends of the keratan sulfate (KS) and chondroitin-6-sulfate (C6S) glycosaminoglycans.

Risk in Pregnancy

c

Adverse effects

Pyrexia, vomiting, headache, nausea, abdominal pain, chills and fatigue.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Patients with acute febrile respiratory illness may be at high risk of fatal complications due to hypersensitivity reactions. Careful consideration should be given to the clinical status of the patient prior to administration.

Interactions

No drug interactions have been observed.

## EMPAGLIFLOZIN

Code	Description	Indications	Route of administration and dosage
010.000.6008.00	TABLET Each tablet contains: Empagliflozin 10 mg Package with 30 tablets.	Treatment of type 2 diabetes mellitus when metformin therapy does not provide adequate glycemic control.	Oral. Adults: 10 mg once a day. Patients who have successfully tolerated 10 mg and require additional glycemic control the dose may be increased to 25 mg once daily.
010.000.6009.00	TABLET Each tablet contains: Empagliflozin 25 mg Package with 30 tablets.		Take in combination with metformin.

Generalities

Sodium-glucose co-transporter 2 (SGLT2) is the predominant transporter responsible for the reabsorption of glucose from the glomerular filtrate, returning it to the circulation. Empagliflozin is an SGLT2 inhibitor, and therefore reduces glucose reabsorption and increases the amount of glucose eliminated in the urine. The action of empagliflozin is independent of the function of pancreatic beta cells and insulin secretion and therefore the risk of producing hypoglycemia is very low. The excretion of glucose in the urine results in a loss of calories, which is associated with a loss of body fat and weight loss.

Risk in Pregnancy

d

Adverse effects

Vaginal moniliasis, vulvovaginitis, balanitis and other genital infections. Urinary tract infection. Hypoglycemia (when used with a sulfonyleurea or insulin). Pruritus (generalized). Hypovolemia. Increased urination, dysuria.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Treatment with empagliflozin should not be initiated in patients with an eGFR less than 60 mL/min/1.73 m<sup>2</sup> or CrCl <60 mL/min. Treatment with empagliflozin should be discontinued when eGFR is consistently below 45 mL/min/1.73 m<sup>2</sup> or CrCl is consistently below 45 mL/min.

Empagliflozin is not effective in patients undergoing dialysis.

Due to its mechanism of action, mainly renal, it is advisable to monitor renal function before starting treatment with empagliflozin and at periodic intervals. Likewise, if other drugs that may affect kidney function are added, this will be adequately monitored.

The fall in volume induced by osmotic diuresis that accompanies glycosuria may affect hydration status, particularly in elderly patients, with a decrease in anterior pressure. Caution should be used in patients for whom an empagliflozin-induced drop in blood pressure could pose a risk, such as patients with known cardiovascular disease, patients on antihypertensive treatment with a history of hypotension, or patients 75 years of age or older. In the case of concomitant diseases that may lead to fluid loss (e.g. diarrhea), close monitoring of blood volume and electrolytes is recommended.

Increased glucose concentrations in the urine can promote infections (cystitis, balanitis, pyelonephritis, urethral sepsis, etc.). In the case of patients with complicated urinary tract infections, temporary interruption of treatment with empagliflozin should be considered.

Interactions

Loop and thiazide diuretics may increase the risk of dehydration and hypotension. No clinically significant interactions were observed when empagliflozin was co-administered with other commonly used medicinal products.

## EMPAGLIFLOZIN/METFORMIN

Clue	Description	Indications	Route of administration and dosage
010.000.6077.00	<p>TABLET</p> <p>Each tablet contains: Empagliflozin 12.5 mg metformin hydrochloride 850 mg</p> <p>Package with 60 tablets.</p>	<p>Treatment complementary to diet and exercise regimen for glycemic control in adults with type 2 diabetes mellitus</p> <p>2 who already receive Empagliflozin and metformin co-administered as tablets with each drug separately.</p>	<p>Oral</p> <p>Adults</p> <p>One tablet twice a day.</p> <p>Dosage should be individualized based on the patient's current regimen, effectiveness and tolerance, without exceeding the maximum recommended daily dose of 25 mg of empagliflozin and 2000 mg of metformin.</p>

### Generalities

Empagliflozin is a competitive, selective, reversible and highly potent inhibitor of SGLT-2, with an IC<sub>50</sub> value of 1.3 nM. It has 5000 times greater selectivity against human SGLT-1 (IC<sub>50</sub> of 6278 nM), responsible for glucose absorption in the intestines. High selectivity was also demonstrated for other glucose transporters (GLUT) responsible for glucose homeostasis in different tissues.

Metformin is a biguanide with antihyperglycemic effects, which reduces both basal and postprandial plasma glucose values. This drug does not stimulate insulin secretion and, therefore, does not cause hypoglycemia.

### Risk in Pregnancy

d

### Adverse effects

Urinary tract infection, vaginal moniliasis, vulvovaginitis, balanitis, frequency, polyuria, nocturia, decreased blood pressure (ambulatory), decreased systolic blood pressure, dehydration, hypotension, hypovolemia, orthostatic hypotension, syncope,

### Contraindications and Precautions

Contraindications: Hypersensitivity to drugs. Moderate to severe kidney failure. Patients > 75 years of age.

Precautions: This product contains lactose so patients with rare hereditary diseases of galactose intolerance, e.g. g., galactosemia, they should not take this medication. Insulin and secretagogues  
Insulin, such as sulfonylureas, may increase the risk of hypoglycemia. Therefore, a dose may be required of insulin or an insulin secretagogue to reduce the risk of hypoglycemia when used in combination with empagliflozin.

### Interactions

The effect of empagliflozin may add to the diuretic effect of thiazide diuretics and loop diuretics, and may increase the risk of dehydration and hypotension. Empagliflozin does not inhibit, inactivate or induce CYP450 isoenzymes. There is an increased risk of lactic acidosis in the event of acute alcohol poisoning, so the consumption of alcohol and medicinal products containing alcohol should be avoided. Cationic agents that are eliminated by renal tubular secretion (e.g., cimetidine) may interact with metformin by competing for renal tubular transport systems that are common to both. Intravascular administration of iodinated contrast media can lead to renal failure, which could result in accumulation of metformin and the risk of development of lactic acidosis.

## EVOLOCUMAB

Clue	Description	Indications	Route of administration and dosage
010.000.6089.00	<p>INJECTABLE SOLUTION</p> <p>Each prefilled syringe contains: Evolocumab 140 mg</p> <p>Container with a syringe prefilled with 1 mL of solution (140 mg/mL).</p>	<p>Primary hypercholesterolemia (heterozygous familial and non-familial) and mixed dyslipidemia in patients with high cardiovascular risk who, despite being treated with statins</p>	<p>Subcutaneous.</p> <p>Adults: 140 mg every 2 weeks.</p>

010.000.6089.01 Package with a pre-filled pen with 1 mL of solution (140 mg/mL).	high intensity, not reach target LDL-C levels.
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#### Generalities

Evolocumab is a human IgG2 monoclonal antibody of recombinant DNA origin expressed in Chinese hamster ovary (CHO) cells. Evolocumab selectively binds to PCSK9 and prevents the binding of circulating PCSK9 to the low-density lipoprotein receptor (LDLR) located on the cell surface of the liver, thereby preventing PCSK9-mediated degradation of LDLR. Increases in liver LDLR levels result in associated reductions in serum LDL-C.

#### Risk in Pregnancy

b

#### Adverse effects

Nasopharyngitis, upper respiratory tract infection, back pain, arthralgia, flu, and nausea.

#### Contraindications and Precautions

Contraindications and precautions: Hypersensitivity to the drug. Hypersensitivity to latex.

#### Interactions

No formal drug-drug interaction studies have been performed for Evolocumab.

## EXENATIDA

Clue	Description	Indications	Route of administration and dosage
010.000.4169.01	<p>INJECTABLE SOLUTION</p> <p>Each mL contains: Exenatide 250 µg.</p> <p>Pen container with 10 µg/dose (60 doses/2.4 mL).</p>	Diabetes mellitus type 2.	<p>Subcutaneous.</p> <p>Adults and people over 18 years of age: Home</p> <p>5 µg every 12 hours for one month.</p> <p>Maintenance.</p> <p>10 µg every 12 hours from the second month of treatment.</p>
010.000.6054.01	<p>INJECTABLE SUSPENSION EXTENDED RELEASE</p> <p>Each prefilled pen contains: Exenatide 2 mg</p> <p>Package with 4 single-dose cases. Each case contains: 1 pen prefilled with powder and 0.65 mL of diluent for needle suspension. A spare needle.</p>		<p>Subcutaneous.</p> <p>Adults and people over 18 years of age: 2 mg once a week.</p>

#### Generalities

Glucagon-like peptide 1 (GLP-1). Incretin mimetic agent that increases glucose-dependent insulin secretion and simulates other antihyperglycemic actions of incretins. Peptide amine 39 amino acids with MW of 4186.6 Daltons.

#### Risk in Pregnancy

c

#### Adverse effects

Diarrhea, dyspepsia, gastroesophageal reflux disease, nausea, vomiting, asthenia, feeling nervous, decreased appetite, dizziness, headache, hyperhidrosis. Risk of pancreatitis in patients with hyperlipidemia. Risk of renal failure with concomitant use with nephrotoxic drugs and in patients dehydrated due to gastroenteritis or use of diuretics.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and type 1 diabetes mellitus.

Precautions: Exenatide is not a substitute for insulin in patients who require it. It should not be used in patients with diabetic ketoacidosis. It should also not be used in patients with type 2 diabetes who require insulin therapy due to beta cell failure. Oral or intravenous hydration in patients dehydrated before of exenatide use.

## Interactions

The decreased rate of gastric emptying as an effect of exenatide may reduce the extent and rate of absorption of orally administered medications. It should be used with caution in patients receiving oral medications that require rapid gastrointestinal absorption. The AUC and Cmax of lovastatin were decreased by approximately 40% and 28%, respectively, and the Tmax was delayed by about 4 hours when exenatide (10 µg BID) was administered concomitantly with single dose lovastatin (40 mg) compared to lovastatin administered alone. In a clinical pharmacology study in healthy volunteers, a delay of approximately 2 hours in Tmax was observed when warfarin was administered 30 minutes after exenatide.

**EZETIMIBA**

Clue	Description	Indications	Route of administration and dosage
	TABLET		
	Each tablet contains: Ezetimibe 10 mg.	Hypercholesterolemia.	Oral.
010.000.4024.00	Package with 7 tablets.		Adults:  10 mg per day, alone or combined with a statin.
010.000.4024.01	Package with 10 tablets.		
010.000.4024.02	Package with 14 tablets.		
010.000.4024.03	Package with 21 tablets.		
010.000.4024.04	Package with 28 tablets.		
010.000.4024.05	Package with 30 tablets.		

## Generalities

It acts on the villi of the small intestine, inhibiting the absorption of cholesterol.

## Risk in Pregnancy

c

## Adverse effects

Angioedema, diarrhea, abdominal pain, arthralgia, fatigue, back pain and cough.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Liver disease.

## Interactions

With cyclosporine it increases its levels.

**EZETIMIBA-SIMVASTATINE**

Clue	Description	Indications	Route of administration and dosage
	COMPRESSED		
	Each tablet contains: Ezetimibe 10 mg. Simvastatin 20 mg.	Hypercholesterolemia primary.	Oral.
010.000.4025.00	Package with 14 tablets.		Adults:  One tablet every 24 hours, at night.
010.000.4025.01	Package with 28 tablets.		

## Generalities

Ezetimibe acts on the villi of the small intestine by inhibiting cholesterol absorption. Simvastatin is an inactive lactone that *in vivo* is rapidly transformed by hydrolysis into the corresponding b-hydroxy acid, which is a potent inhibitor of HMG-CoA reductase.

## Risk in Pregnancy

x

## Adverse effects

With ezetimibe frequently abdominal pain, diarrhea, fatigue, flu-like symptoms, muscle cramps; Rarely cutaneous and subcutaneous disorders, hypersensitivity reactions including angioneurotic edema and rash.

With simvastatin frequently anemia, abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, vomiting, pancreatitis, hepatitis-jaundice, muscle cramps, myopathy, rhabdomyolysis, paresthesias, peripheral neuropathy, alopecia, pruritus, rash. Rarely, hypersensitivity syndrome such as angioneurotic edema, lupoid syndrome, polymyalgia rheumatica, dermatomyositis, vasculitis, thrombocytopenia, eosinophilia, increased erythrocyte sedimentation rate, arthritis and arthralgia, urticaria, photosensitivity, fever, flushing, dyspnea and general malaise.

## Contraindications and Precautions

Contraindications: Hypersensitivity to any of the components of the medication. Active liver disease or unexplained persistent elevation of serum transaminases. Pregnancy and breastfeeding.

Precautions: In mild liver failure. Discontinue immediately in case of significant increase in liver enzymes (hepatitis) and muscle enzymes (myopathy, rhabdomyolysis).

#### Interactions

Ezetimibe does not induce cytochrome P-450 drug-metabolizing enzymes. No clinically important interaction has been observed between ezetimibe and drugs that are metabolized by cytochromes P-450 1A2 2D6 2C8 2C9 and 3A4 or by acetyltransferase. Simvastatin is metabolized by CYP3A4 but does not inhibit its activity; Therefore, it is not expected to affect the plasma concentrations of other drugs metabolized by CYP3A4. Strong CYP3A4 inhibitors increase the risk of myopathy by decreasing the elimination of the simvastatin component (Itraconazole, ketoconazole, erythromycin, clarithromycin, HIV protease inhibitors, nefazodone, cyclosporine). With diltiazem, amiodarone, verapamil, gemfibrozil and niacin, the risk of myopathy increases. Antacids and cholestyramine decrease the absorption of ezetimibe.

## FENOFIBRATE

Clue	Description	Indications	Route of administration and dosage
010.000.6134.00 010.000.6134.01	CAPSULE  Each capsule contains: Fenofibrate 200 mg  Container with 14 capsules. Container with 28 capsules.	Reduction in progression of proliferative diabetic retinopathy No patients with in type 2 diabetes mellitus.  Hypercholesterolemia and Hypertriglyceridemia alone or combined as well as dyslipidemia type III and V	Oral.  Adults: 200 mg or 160 mg every 24 hours with food
010.000.6276.01	CAPSULE  Each capsule contains: Fenofibrate 160 mg  Box with 30 capsules.		

#### Generalities

Derived from fibric acid whose lipid-modifying effects reported in humans are mediated through the activation of the Peroxisome Proliferated Activated Receptor, type alpha (PPAR $\alpha$ ). Through activation of PPAR $\alpha$ , fenofibrate increases lipolysis and clearance of atherogenic triglyceride-rich particles from plasma by activating lipoprotein lipase and reducing apoprotein CIII production. These effects of fenofibrate on lipoproteins lead to a reduction in very low and low density ("VLDL") fractions, and "LDL") that contain apoprotein B and an increase in the fraction of high-density lipoprotein (HDL) that they contain apoproteins AI and AII.

#### Risk in Pregnancy

X

#### Adverse effects

Abdominal pain, nausea, vomiting, diarrhea, flatulence, increased transaminases, increased homocysteine levels.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Known photoallergy or phototoxic reaction during treatment with fibrates or ketoprofen; in cases of liver and/or kidney damage; as well as in the presence of known gallbladder disease and/or chronic pancreatitis.

Precautions: Before considering fenofibrate therapy, the secondary cause of hyperlipidemia should be treated such as: uncontrolled type 2 diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemia, obstructive liver disease, drug treatment, alcoholism. For patients with hyperlipidemia taking estrogens or estrogen-containing contraceptives, it should be confirmed whether the hyperlipidemia is primary or secondary in nature (possible increase in lipid values caused by oral estrogens).

#### Interactions

Fenofibrate increases the effect of the oral anticoagulant and may increase the risk of bleeding. It is advisable to reduce the dose of anticoagulants by approximately one third at the beginning of treatment and then gradually adjust it, if necessary, based on INR monitoring.

Some severe cases of reversible deterioration of renal function have been reported during concomitant administration of fenofibrate and cyclosporine. Therefore, the renal function of these patients should be closely monitored.

patients and suspend treatment with fenofibrate in case of severe alteration of laboratory parameters.

The risk of severe muscle disease is increased if a fibrate is used concomitantly with HMG-CoA reductase inhibitors or other fibrates. This combination therapy should be used with caution and patients should be closely monitored for evidence of muscle toxicity.

Some cases of paradoxical reversible reduction of HDL cholesterol have been reported during concomitant administration of fenofibrate and glitazones. Therefore, it is recommended to monitor HDL cholesterol when one of these components is added to the other and suspend any of the therapies when HDL cholesterol is very low.

Patients with co-administration of fenofibrate and drugs metabolized by CYP2C, CYP2A6 and, especially, CYP2C9 with a reduced therapeutic index, should be carefully monitored and it is advisable, if necessary, to adjust the dose of these drugs.

## FLUDROCORTISONE

Clue	Description	Indications	Route of administration and dosage
010.000.4160.00	COMPRESSED  Each tablet contains: Fludrocortisone acetate 0.1 mg.  Package with 100 tablets.	Insufficiency chronic adrenocortical.  Adrenogenital syndrome with salt loss.	Oral.  Adult:  100 µg every 24 hours; decrease to 50 µg every 24 hours, if high blood pressure occurs.  Children:  50 to 100 µg every 24 hours.

### Generalities

Synthetic glucocorticoid with very high mineralocorticoid activity and moderate glucocorticoid activity.

### Risk in Pregnancy

C

### Adverse effects

Arterial hypertension, anaphylactic reaction, vertigo, congestive heart failure, severe headache, hypokalemia and peripheral edema.

### Contraindications and Precautions

Contraindications: Hypersensitivity to fludrocortisone.

Precautions: Consider risk benefit in patients with congestive heart failure, high blood pressure, impaired kidney function, during pregnancy and lactation. Treatment should not be stopped abruptly.

### Interactions

With digitalis it can cause cardiac arrhythmias. With diuretics the hypokalemic effect is intensified.

## FLUVASTATIN

Clue	Description	Indications	Route of administration and dosage
010.000.4244.01	CAPSULE  Each capsule contains: Fluvastatin sodium equivalent to 20 mg fluvastatin.  Container with 28 capsules.	Hypercholesterolemia primary.	Oral.  Adults:  20 to 40 mg every 24 hours, at night.

### Generalities

Competitive inhibitor of HMG-CoA reductase, with greater effect in reducing LDL.

### Risk in Pregnancy

X

### Adverse effects

Constipation, nausea, flatulence, dyspepsia, abdominal pain, headache, myalgia, asthenia and insomnia.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, pregnancy, lactation and active liver disease.

Precautions: Therapeutic with fibrates and niacin.

### Interactions

Cimetidine, ranitidine and omeprazole increase the bioavailability of fluvastatin. Rifampin decreases it.

**GALSULPHASE**

Clue	Description	Indications	Route of administration and dosage
010.000.5543.00	<p>INJECTABLE SOLUTION</p> <p>Each vial contains: Galsulfase 5 mg.</p> <p>Package with a vial with 5 mL (1 mg/mL).</p>	<p>replacement therapy enzymatic for Mucopolysaccharidosis VI (Maroteaux-Lamy Disease).</p>	<p>Intravenous.</p> <p>Children, adolescents and adults 1.0 mg/Kg of body weight, once a week, administered in solution over 4 hours.</p> <p>Galsulfase should be diluted in 0.9% saline, to a total volume of 250 mL. In subjects weighing &lt; 20 kg susceptible to fluid overload, the total volume can be reduced to 100 mL.</p> <p>It is recommended to administer 2.5% of the volume in the first hour, and the remaining 97.5% over the following three hours.</p>

**Generalities**

Galsulfase has been developed with the purpose of offering a treatment for MPS VI, by replacing the deficient enzyme, N-acetylgalactosamine 4-sulfatase (aryl sulfatase B), thereby reducing the abnormal accumulation of GAG that is the cause of the deleterious effects to the disease.

**Risk in Pregnancy**

c

**Adverse effects**

Pharyngitis, gastroenteritis, areflexia, conjunctivitis, corneal opacity, otalgia, hypertension, dyspnea, apnea, nasal congestion, abdominal pain, umbilical hernia, facial edema, chest pain, tremors, general malaise.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug.

Precautions: Sleep apnea is common in patients with MPS VI, and prior treatment with antihistamines may increase the risk of apnea episodes. Assessment of airway patency should be considered before initiation of treatment. Patients using oxygen or continuous positive airway pressure airways during sleep should have these devices readily available during the infusion, in the event of a possible reaction or excessive drowsiness/sleepiness induced by the use of antihistamine.

In MPS VI, symptoms related to airway obstruction and anatomical characteristics such as craniofacial alterations, short neck, stiffness of the faciocervical joints, and anterolaterally positioned larynx are factors that complicate laryngoscopy and intubation. A careful evaluation of the cardiovascular and respiratory system is required before performing procedures such as sedation or anesthesia; An otolaryngologist should be involved in these procedures.

**Interactions**

No interaction studies have been performed, nor have they been identified in clinical experience with the product.

**CHORIONIC GONADOTROPHIN**

Clue	Description	Indications	Route of administration and dosage
010.000.1081.00	<p>INJECTABLE SOLUTION</p> <p>Each vial or vial with lyophilisate contains:</p> <p>Chorionic gonadotropin 5,000 IU.</p> <p>Container with 1 vial and vial with 2 mL of diluent.</p>	<p>Ovulation inducer in case of female infertility.</p> <p>Hypogonadism.</p> <p>Cryptorchidism not obstructive.</p>	<p>Intramuscular or subcutaneous.</p> <p>Adults: Women: 5,000 to 10,000 IU, one day after the last dose of urophylotropin or 5 to 12 days after the last dose of clomiphene.</p> <p>Men: 1,000 to 4,000 IU three times a week for 3 to 9 months.</p>
010.000.1081.01	<p>Package with 1 or 3 ampoules or vials and 1 or 3 ampoules with 1 mL of diluent.</p>	<p>Feminine infertility.</p> <p>Hypogonadism.</p>	<p>Children: 1,000 to 5,000 IU every third day. Administer 4 doses. Subcutaneous.</p>
010.000.1081.02	<p>INJECTABLE SOLUTION</p> <p>Each vial with lyophilisate contains:</p> <p>Chorionic gonadotropin 250 yg.</p> <p>Container with a vial with lyophilisate and a vial or vial with 1 mL of diluent.</p>	<p>Hypogonadotrophic.</p>	<p>Women with anovulation or oligoovulation:  250 yg 24-48 hours after the last application of FSH or after the last dose of clomiphene, when optimal stimulation of development has been achieved</p>



follicular.

Women undergoing assisted reproduction techniques:

250  $\mu$ g 24-48 hours after the last FSH application, when optimal stimulation of follicular development has been achieved.

Hypogonadotropic hypogonadism:

250  $\mu$ g twice a week alternating with FSH (75 to 150 IU) three times to stimulate week. For  
Spermatogenesis requires 12 weeks of treatment.

**Generalities**

Hormone substitute that stimulates ovulation of a mature follicle and the production of androgens in the cells of the Leydig.

**Risk in Pregnancy**

c

**Adverse effects**

Pain at the injection site, precocious puberty, headache, irritability, depression.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug, pituitary and gonadal tumors, ovarian dystrophy, precocious puberty and androgen-dependent tumors.

**Interactions**

With luteinizing hormone and follicle stimulating ovulation is promoted.

**ICATIBANT**

Clue	Description	Indications	Route of administration and dosage
010.000.5990.00	<p>INJECTABLE SOLUTION</p> <p>Each prefilled syringe contains: Icatibant acetate equivalent to 30 mg icatibant</p> <p>Package with a prefilled syringe with 3 mL (10 mg/mL).</p>	<p>Symptomatic treatment of acute attacks of hereditary angioedema (HAE), with C1 esterase inhibitor deficiency.</p>	<p>Subcutaneous, in the abdominal area.</p> <p>Adults and people over 18 years of age. 30 mg.</p>

**Generalities**

Synthetic decapeptide with five non-proteinogenic amino acids. Selective competitive antagonist of the bradykinin B2 receptor, with a similar affinity to bradykinin.

**Risk in Pregnancy**

c

**Adverse effects**

Injection site reaction, pyrexia, elevated transaminases, nervous system disorders, dizziness.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug.  
Precautions: During acute coronary ischemia, unstable angina, or in the weeks following an accident Cerebral Vascular.

**Interactions**

Metabolic drug interactions are not expected between Icatibant and CYP450 substrates, inhibitors and inducers.

**IDURSULFASA**

Clue	Description	Indications	Route of administration and dosage
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010.000.5550.00	INJECTABLE SOLUTION	Hunter syndrome (Mucopolysaccharidosis II).	Intravenous infusion.
	Each vial contains: Idursulfase 6 mg.		Adults and children 5 years of age and older:  0.5 mg/Kg of body weight, administered weekly.
	Container with vial bottle with 3 mL (6 mg/3 mL).		Dilute in 100 mL of 0.9% sodium chloride solution. Manage in a period of 1 to 3 hours.

#### Generalities

Idursulfase is a purified form of the lysosomal enzyme iduronate-2-sulfatase, which functions to catabolize the glycosaminoglycans dermatan sulfate and heparan sulfate, by cleavage of the sulfate groups linked to the oligosaccharides.

#### Risk in Pregnancy

c

#### Adverse effects

Difficulty breathing, hypoxia, hypotension, seizure, loss of consciousness, angioedema of the throat or tongue, hypertension, dyspepsia, urticaria, rash, pruritus.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the medication.

Precautions: Patients with severe underlying respiratory tract disease.

#### Interactions

No formal drug interaction studies have been performed.

## IMIGLUCERase

Clue	Description	Indications	Route of administration and dosage
010.000.5545.00	INJECTABLE SOLUTION	Gaucher disease non-neuropathic (Type I)	Intravenous infusion.
	Each vial with powder contains:  Imiglucerase 400 U.	Chronic neuropathic disease (Type III) due to deficiency of the enzyme Glucocerebrosidase.	Children, adolescents and adults: 60 U/kg of body weight, once every 2 weeks, in the first months. Then adjust the dose according to the patient's response to treatment.
	Container with vial bottle with lyophilized powder.		For neuropathic or type III Gaucher disease, 120 U/kg of body weight, once every 2 weeks, and up to 240  U/Kg of body weight, once every 2 weeks.  Administer diluted in 0.9% sodium chloride intravenous solutions, packaged in glass bottles (dilute the reconstituted dose in a volume of 100 to 200 mL).
			Administer the solution for 1 to 2 hours. Speed not exceeding 1 unit per kg of body weight per minute.

#### Generalities

Enzyme analogue of the human glucocerebrosidase enzyme, Imiglucerase, purified by recombinant DNA technology using live Chinese hamster ovary cell cultures. Imiglucerase acts on the underlying cause of Gucher's disease Type I and III, due to the deficiency, lack or malfunction of the enzyme Glucocerebrosidase which catabolizes the hydrolysis of glycolipids (glucosyl-ceramide).

#### Risk in Pregnancy

c

#### Adverse effects

Nausea, vomiting, abdominal pain, diarrhea, dizziness, headache, paresthesia, tachycardia, cyanosis, facial redness, hypotension, respiratory symptoms and arthralgia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Severe allergic-type hypersensitivity reactions. Patients who have developed antibodies or symptoms of hypersensitivity to Imiglucerase.

## Interactions

No interaction studies have been performed.

**HUMAN C1 ESTERASE INHIBITOR**

Clue	Description	Indications	Route of administration and dosage
010.000.6055.00	<p>INJECTABLE SOLUTION</p> <p>Each vial contains: Human C1 esterase inhibitor 500 IU</p> <p>Container with vial bottle with lyophilisate and vial bottle with 10 mL of diluent.</p>	<p>Hereditary angioedema (HAE) due to INH-C1 deficiency types 1 and 2.</p> <p>Treatment of acute episodes.</p>	<p>Intravenous.</p> <p>Adults and children over 3 years of age: 20 IU/Kg of body weight.</p>

## Generalities

The C1 esterase inhibitor belongs to the inhibitory system of serine proteases (serpins) in human plasma, like other proteins such as antithrombin III, alpha-2-antiplasmin, alpha-1-antitrypsin and others.

## Risk in Pregnancy

c

## Adverse effects

Elevation of temperature, reactions at the injection site, tachycardia, flushing, urticaria, dyspnea, headache, dizziness and nausea. Development of thrombosis in treatment attempts with high doses for the prophylaxis or treatment of Capillary Drip Syndrome before, during or after cardiac surgery according to extracorporeal circulation.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the biological.

## Interactions

No interaction studies have been performed.

**ASPARTIC INSULIN AND/OR ASPARTE**

Clue	Description	Indications	Route of administration and dosage
010.000.4156.01	<p>INJECTABLE SOLUTION</p> <p>Each mL contains: Insulin aspartic and/or aspart (recombinant DNA origin) 100 IU.</p> <p>Pre-filled pen with 3 mL.</p>	<p>Mellitus diabetes.</p>	<p>Intravenous or subcutaneous.</p> <p>Adults: Dose according to the patient's requirement 3 or more times a day.</p>

## Generalities

Insulin aspart is identical to natural human insulin, causes rapid transport of glucose and amino acids from the cell, promotes the uptake and storage of glucose in the form of glycogen in the liver, inhibits gluconeogenesis, promotes the conversion of excess glucose in fats.

## Risk in Pregnancy

b

## Adverse effects

Allergic reactions, lipodystrophy and hypoglycemia.

## Contraindications and Precautions

Contraindications: hypersensitivity to the drug, hypoglycemia.

Precautions: Inappropriate dosing or discontinuation of treatment, especially in type 1 patients, leads to hyperglycemia and diabetic ketoacidosis. Skipping a meal or engaging in unplanned exercise  
Strenuous exercise can lead to hypoglycemia.

**INSULIN ASPARTA / INSULIN ASPARTA PROTAMINE)**

Clue	Description	Indications	Route of administration and dosage
010.000.6117.01	<p>INJECTABLE SUSPENSION</p> <p>Each mL contains: Insulin aspart of recombinant DNA origin (30% soluble insulin aspart and 70% crystalline protamine insulin aspart) 100 U</p> <p>Container or cardboard box with 5 prefilled or prefilled pens with 3 mL (100 U/ mL).</p>	Mellitus diabetes.	<p>Subcutaneous.</p> <p>Adults: Dosage according to the patient's needs.</p> <p>In type 2 diabetes mellitus it can be administered as monotherapy or in combination with oral antidiabetics. The initial dose is 6 U with breakfast and 6 U with snack. It is also possible to start treatment by administering</p> <p>12 U once a day.</p> <p>In type 1 diabetes mellitus, the individual insulin need is usually between 0.5 to 1.0 U/Kg of body weight/day.</p>

**Generalities**

The blood glucose-lowering effect of insulin occurs when the molecules facilitate glucose uptake by binding to insulin receptors on muscle and fat cells, while inhibiting glucose production by the liver. .

Insulin aspart containing 30% soluble insulin aspart, which begins to act quickly, and 70% insulin aspart crystallized with protamine, which has an activity profile similar to that of human NPH insulin.

**Risk in Pregnancy**

c

**Adverse effects**

Hypoglycemia, urticaria, rashes, rash, diabetic retinopathy, lipodystrophy, edema.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the biological.

Precautions: Hypoglycemia.

**Interactions**

The following substances may reduce the patient's insulin requirements: oral antidiabetics (ADOs), angiotensin-converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.

The following substances may increase the patient's insulin requirements: oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

Beta blockers may mask hypoglycemic symptoms. Octreotide/lanreotide can either increase or decrease insulin requirements. Alcohol consumption can intensify or reduce the effects insulin hypoglycemia.

**INSULIN DEGLUDEC**

Clue	Description	Indications	Route of administration and dosage
010.000.6316.00	<p>INJECTABLE SOLUTION</p> <p>Each mL contains: Insulin degludec (DNA origin recombinant) 100 U</p> <p>Cardboard box with 1 pre-filled pen with 3 mL.</p>	Diabetes mellitus type 1 in adolescents and children from 1 year of age.	<p>Subcutaneous</p> <p>100 units/mL a dose of 1-80 units can be administered per injection, in steps of 1 unit.</p> <p>It is administered once a day.</p>
010.000.6316.01	<p>Each cardboard with 5 pens prefilled with 3 mL.</p>		

**Generalities**

Ultra-long-acting basal insulin to be used once a day at any time of the day.

It specifically binds to the human insulin receptor and results in the same pharmacological effect as human insulin. The blood glucose-lowering effect of this insulin is due to facilitated glucose uptake following binding of insulin to receptors in muscle and fat cells and simultaneous inhibition of glucose production in the liver.

**Risk in Pregnancy**

b

**Adverse effects**

Immune system disorders, hypoglycemia, lipodystrophy, injection site reactions.

**Contraindications and Precautions**

Contraindications: hypersensitivity to the active substance or to any of the excipients. Precautions: hypoglycemia, hyperglycemia, effects on the ability to drive and use machinery.

**Interactions**

Substances that reduce the need for insulin: Oral antidiabetic medicinal products, GLP-1 receptor agonists, monoamine oxidase inhibitors (MAOIs), beta blockers, angiotensin-converting enzyme (ACE) inhibitors, salicylates, steroids, anabolics and sulfonamides.

Substances that may increase insulin requirements: oral contraceptives, thiazides, glucocorticoids, thyroid hormones, growth hormone, danazol.

Beta blockers can mask the symptoms of hypoglycemia.

Octreotide/Lanreotide may increase or decrease insulin requirements.

Alcohol can intensify or reduce the hypoglycemic effect of insulin.

**INSULIN DETEMIR**

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION	Mellitus diabetes.	Subcutaneous.
	Each mL contains: Insulin detemir (insulin analogue of recombinant DNA origin) 100 U.		Adults: Dose: according to the patient's requirement.
010.000.4165.00	Container or cardboard box with 1 prefilled or prefilled pen with 3 mL (100 U/mL).		
010.000.4165.01	Container or cardboard box with 5 prefilled pens. or prefilled with 3 mL (100 U/mL).		

**Generalities**

Insulin detemir is derived from human insulin by deletion of the B30 residue and acylation of the Lys series-side amino group.  
<sup>B29</sup> by the natural occurrence of tetradecanoic fatty acid. The prolonged action of insulin is mediated by self-association of its molecules to the injection site and albumin binding via the fatty acid side chain. The absorption rate is limited by the low concentration of insulin available by diffusion through the tissue and passage through the capillary wall.

**Risk in Pregnancy**

b

**Adverse effects**

Cold sweating, pale skin, feeling of fatigue, nervousness, anxiety, tremor, confusion, excessive feeling of hunger, temporary changes in vision, headache, nausea and tachycardia.

**Contraindications and Precautions**

Contraindications: Patients with hypoglycemia, history of hypersensitivity to the components of the formula.

**Interactions**

The hypoglycemic effect may be increased by: oral hypoglycemic agents, MAO inhibitors, alcohol, non-selective beta-blocking agents, ACE inhibitors, salicylates, sulfonamides, octreotide.

The hypoglycemic effect can be reduced by: oral contraceptives, thiazides, corticosteroids, thyroid hormones, sympathomimetics and danazol.

**INSULIN GLARGINE**

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION	Diabetes mellitus type 1	Subcutaneous.
	Each mL of solution contains: Insulin glargine 3.64 mg equivalent to 100.0 IU of human insulin.	Diabetes mellitus type 2.	Adults: Once a day, at night. The dose must be adjusted individually at the discretion of the specialist.
010.000.4158.00	Container with a vial bottle with 10		

010.000.4158.01	mL. Container with 5 glass cartridges with 3 mL in disposable device.		
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#### Generalities

Analogue of human insulin that has low solubility at neutral pH. At acidic pH (pH 4) it is completely soluble. After subcutaneous injection, the acid solution is neutralized, causing the formation of microprecipitates from which small amounts of insulin glargine are continuously released, giving rise to a uniform concentration without peaks with a prolonged duration of action.

#### Risk in Pregnancy

b

#### Adverse effects

Allergic reactions, lipodystrophy, hypokalemia and hypoglycemia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to insulin glargine or any of the components of the formula.  
Precautions: Kidney and liver failure. Beta blockers mask the symptoms of hypoglycemia.

#### Interactions

Oral antidiabetics, ACE inhibitors, salicylates, disopyramide, fibrates, fluoxetine, MAO inhibitors, pentoxifylline, propoxyphene and sulfonamide antibiotics may increase the hypoglycemic effect and susceptibility to hypoglycemia. Corticosteroids, danazol, diazoxide, diuretics, glucagon, isoniazid, somatotropin phenothiazine derivatives, thyroid hormones, estrogens and progestogens, protease inhibitors and atypical antipsychotic medications such as olanzapine and clozapine can reduce the hypoglycemic effect. Beta blockers, clonidine, lithium salts and alcohol can enhance or weaken the hypoglycemic effect. Pentamidine can cause hypoglycemia, which may sometimes be followed by hyperglycemia.

## INSULIN LISPRO

Clue	Description	Indications	Route of administration and dosage
010.000.4162.00	INJECTABLE SOLUTION.  Each mL contains: Insulin lispro (DNA origin recombinant) 100 IU.  Container with a 10 mL vial.	Diabetes mellitus type 1.	Subcutaneous.  Adult and children:  The dose is established according to the patient's needs.

#### Generalities

Insulin analogue, with the same stability as regular human insulin, but with much faster absorption, which provides it with a more physiological profile.

#### Risk in Pregnancy

b

#### Adverse effects

Allergic reactions, lipodystrophy, hypokalemia and hypoglycemia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and hypoglycemia.  
Precautions: Kidney and liver failure. Beta blockers mask the symptoms of hypoglycemia.

#### Interactions

Oral contraceptives, corticosteroids and thyroid hormones reduce the hypoglycemic effect. Salicylates, sulfonamides and inhibitors of monoamine oxidase and angiotensin-converting enzyme and increase the hypoglycemic effect.

## INSULIN LISPRO. LISPRO PROTAMINE

Clue	Description	Indications	Route of administration and dosage
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010.000.4148.01	INJECTABLE SUSPENSION	Insulin-dependent diabetes mellitus.	Subcutaneous.  Adults: At the discretion of the specialist doctor and in accordance with the patient's needs.
	Each mL contains: Insulin lispro (DNA origin recombinant) 25 IU Insulin lispro protamine (DNA origin recombinant) 75 IU  Container with a 10 mL vial.		

#### Generalities

Insulin analogue, with the same stability as regular human insulin, but with much faster absorption, which provides it with a more physiological profile.

#### Risk in Pregnancy

b

#### Adverse effects

Allergic reactions, lipodystrophy, hypokalemia and hypoglycemia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, hypoglycemia.  
Precautions: Kidney and liver failure. Beta blockers mask the symptoms of hypoglycemia.

#### Interactions

Oral contraceptives, corticosteroids and thyroid hormones reduce the hypoglycemic effect. Salicylates, sulfonamides and monoamine oxidase and angiotensin-converting enzyme inhibitors increase the hypoglycemic effect.

## LANREOTIDA

Clue	Description	Indications	Route of administration and dosage
010.000.5610.00	INJECTABLE SOLUTION  Each prefilled (ready to use) syringe contains:  Lanreotide acetate equivalent to 90 mg lanreotide:  Package with a prefilled syringe with 0.3 mL.	Acromegaly and tumors neuroendocrine.	Deep subcutaneous.  Adults: Acromegaly. 60 to 120 mg every 28 days. Neuroendocrine tumors. Initial dose: 60 to 120 mg every 28 days. If the response is insufficient, the dose can be adjusted to 120 mg every 28 days. Extended treatment: In patients well controlled with somatostatin analogues, they can be treated with lanreotide 120 mg every 42 or 56 days.
010.000.5610.01	Package with a 0.5 mL prefilled syringe with safety device.		
010.000.5611.00	INJECTABLE SOLUTION  Each prefilled (ready to use) syringe contains:  Lanreotide acetate equivalent to 120 mg lanreotide  Package with a prefilled syringe with 0.5 mL.		The injection must be administered by a health professional. However, for patients treated for acromegaly or neuroendocrine tumors who receive a continuous stable dose, the product can be administered by the patient or by a trusted person with prior training from a healthcare professional.
010.000.5611.01	Package with a 0.5 mL prefilled syringe with safety device.		

#### Generalities

Lanreotide is an octapeptide analogue of human somatostatin. Like natural somatostatin, Lanreotide is an inhibitor of various exocrine and paracrine endocrine functions. Lanreotide is much more active than natural somatostatin and has a much longer duration of action.

#### Risk in Pregnancy

c

#### Adverse effects

Fatigue, headache, vertigo, bradycardia, hypoglycemia and hyperglycemia, diarrhea, abdominal pain, nausea, vomiting, dyspepsia, flatulence, acute pancreatitis, steatorrhea, gallstones, increased bilirubin, anemia, weight loss.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Lanreotide may reduce gallbladder motility and cause gallstones. Patients should be monitored frequently.

Patients treated with Lanreotide Autogel may experience hypoglycemia or hyperglycemia.

Slight decreases in thyroid function have been observed during treatment in patients with acromegaly.

Caution should be exercised when initiating treatment with lanreotide in patients with bradycardia.

### Interactions

Insulin, oral hypoglycemic medications, cyclosporine. Lanreotide acetate may reduce intestinal absorption of concomitantly administered drugs.

## LARONIDASE

Clue	Description	Indications	Route of administration and dosage
010.000.5547.00	<p>INJECTABLE SOLUTION</p> <p>Each vial contains: Laronidase 2.9 mg (500 U).</p> <p>Container with vial with 5 mL (2.9 mg or 500 U).</p>	<p>Disease of Mucopolysaccharidosis Type I due to deficiency of the enzyme Alpha-L-Iduronidase.</p>	<p>Intravenous infusion.</p> <p>Children, adolescents and adults: 0.58 mg (100 U)/kg body weight, once every week.</p> <p>Administer diluted in intravenous solutions of 0.9% sodium chloride, packaged in glass bottles (bring the reconstituted dose to a volume of 100 mL if the patient's weight is <math>\leq</math> 20 kg or 250 mL if the patient's weight is <math>&gt;</math> 20 kg).</p> <p>Initial rate of 0.0116 mg (2 U)/kg body/hour, increase weight gradually every 15 minutes, if tolerated, to a maximum of 0.2494 mg (43 U)/kg body weight/hour.</p> <p>Total administration time 3-4 hours.</p>

### Generalities

Enzyme analogue of the human enzyme alpha-L-Iduronidase, Laronidase, purified by DNA technology recombinant using live Chinese hamster ovary cell cultures. Laronidase acts on the underlying cause of Mucopolysaccharidosis Type I disease, due to the deficiency, lack or malfunction of the enzyme Alpha-L-Iduronidase which catabolizes the hydrolysis of glycominglycans from heparan sulfate and dermatan sulfate.

### Risk in Pregnancy

C

### Adverse effects

Abdominal pain, headache, rash, dyspnea, arthralgia, back pain, tachycardia, pyrexia, chills.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Reactions associated with infusion and readministration after stopping treatment.

### Interactions

No interaction studies have been performed. Chloroquine or procaine due to the risk of interference with intracellular reuptake of laronidase. Risk of interference with the intracellular uptake of laronidase: with chloroquine and procaine.

## LEVOTHYROXINE

Clue	Description	Indications	Route of administration and dosage
	<p>TABLET</p> <p>Each tablet contains: Levothyroxine sodium equivalent to 100 µg levothyroxine sodium</p>	<p>Hypothyroidism.</p>	<p>Oral.</p> <p>Adults: Dose: 50 µg/day, increase at intervals of 25 to 50 µg a day for two to four</p>



010.000.1007.00	anhydrous. Package with 100 tablets.	weeks until the therapeutic effect is achieved. Maximum dose 200 µg/day.  Children: From 6 months 8 to 10 µg /kg body weight/day.  From 6 to 12 months 6 to 8 µg/kg body weight/day.  From 1 to 5 years: 5 to 6 µg/kg body weight/day.  From 6 to 12 years: 4 to 5 µg/kg body weight/day.  Administration is as a single dose.
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#### Generalities

Thyroid hormone that intervenes in protein metabolism and body and brain development.

#### Risk in Pregnancy

TO

#### Adverse effects

Tachycardia, cardiac arrhythmias, angina pectoris, nervousness, insomnia, tremor, weight loss and menstrual irregularities.

#### Contraindications and Precautions

Contraindications: Adrenal insufficiency, hyperthyroidism, euthyroidism, acute myocardial infarction.  
Precautions: Cardiovascular disease, diabetes mellitus and diabetes insipidus.

#### Interactions

Phenytoin, acetylsalicylic acid, adrenergics, tricyclic and digitalis antidepressants increase its effect. Cholestyramine decreases it.

### LEVOTHYROXINE SODIUM

Clue	Description	Indications	Route of administration and dosage
010.000.6169.00	TABLET  Each tablet contains: Levothyroxine sodium 25 µg  Package with 50 tablets.	For the treatment of hypothyroidism.	Oral.  Adults: Mild hypothyroidism: initial dose 50µg/day, increasing every 2 to 4 weeks until the desired dose is obtained.  Patients with sudden onset of hypothyroidism can be administered initial doses of 100 to 200 µg/day.  maintenance dose of 100 to 200 µg/day (1.7 µg/Kg body weight/day) although some patients may require higher doses.  Severe hypothyroidism: initial dose of 12.5-25 µg/day, increasing from 25 to 50 µg/day at intervals of 2 to 4 weeks until adequate response is obtained.  Children Maintenance dose: From 0 to 3 months 10-15 µg/kg body weight/day.  From 3 to 6 months 25-50 µg per day or 8-10 µg/Kg body weight/day. From 6-12 months 50-75 µg per day or 6-8 µg/Kg body weight/day. From 1-5 years old 75-100 µg per day or 5-6 µg/Kg of body weight/day. From 6-12 years 100-150 µg per day or 4-5 µg/Kg body weight/day. After 12 years 150 µg per day or 2-3 µg/Kg body weight/day.

#### Generalities

Thyroid hormone that intervenes in protein metabolism and body and brain development.

#### Risk in Pregnancy

TO

#### Adverse effects

Cardiac arrhythmias, tachycardia, palpitations, angina pectoris, headache, muscle weakness, cramps, flushing, fever, vomiting, menstruation disorders, pseudotumor cerebri, tremor, restlessness, insomnia, hyperhidrosis, weight loss, diarrhea, fatigue, increased appetite, heat intolerance, hyperactivity, anxiety, irritability, emotional lability, increased blood pressure, heart failure, heart attack, colic, hair loss, angioedema.

#### Contraindications and Precautions

Contraindications: Adrenal insufficiency, untreated pituitary insufficiency, subclinical thyrotoxicosis, acute myocardial infarction, acute myocarditis or acute pancarditis.

Precautions: Coronary insufficiency, angina pectoris, arteriosclerosis, hypertension, pituitary insufficiency or adrenal insufficiency, psychotic disorders, coronary insufficiency, heart failure or arrhythmias due to tachycardia.

In postmenopausal women.

#### Interactions

Antidiabetic medications, coumarin derivatives, phenytoin, salicylates, dicumarol, furosemide, clofibrate, orlistat, sevelamer, tyrosine kinase inhibitors, ion exchange resins, aluminum iron and calcium salts, propylthiurasil, glucocorticoids, betasympatholytics, and contrast media containing iodine, amiodarone, sertraline, chloroquine/proguanil, enzyme inducers such as barbiturates, medicinal products leading to liver enzyme induction, estrogens, ferrous sulfate, 5-fluorouracil, tamoxifen, tri/tetracyclic antidepressants.

## LINAGLIPTIN

Clue	Description	Indications	Route of administration and dosage
010.000.5621.00	<p>TABLET</p> <p>Each tablet contains: Linagliptin 5 mg.</p> <p>Package with 30 tablets.</p>	Adjuvant treatment from Type 2 diabetes mellitus, to failure of metformin and sulfonylureas.	<p>Oral.</p> <p>Adults: 5 mg every 24 hours. Single, fixed dose, as monotherapy or in combination treatment with metformin, sulfonylureas, thiazolidinediones.</p>

#### Generalities

Inhibitor of the enzyme DPP-4 (Dipeptidyl peptidase 4), an enzyme that participates in the inactivation of the incretin hormones GLP-1 and GIP (glucagon-like peptide 1, glucose-dependent insulinotropic polypeptide). Both incretin hormones participate in physiological regulation. of glucose homeostasis.

#### Risk in Pregnancy

c

#### Adverse effects

Hypoglycemia, nausea, vomiting, vertigo.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: It should not be used in patients with Type 1 Diabetes, nor for the treatment of diabetic ketoacidosis.

Hypoglycemia.

#### Interactions

Clinical data suggest that the risk of clinically significant interactions with co-administered medicinal products is low. No clinically significant interactions requiring dose adjustment were observed.

Linagliptin had no clinically relevant effects on the pharmacokinetics of metformin, glibenclamide, simvastatin, Pioglitazone, warfarin, Digoxin, or oral contraceptives, providing in vivo evidence of a low propensity to cause drug interactions with substrates of CYP3A4, CYP2C9, CYP2C8, P-glycoprotein, and the organic cationic transporter.

## LINAGLIPTIN/METFORMIN

Clue	Description	Indications	Route of administration and dosage
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010.000.5740.00	<p>TABLET</p> <p>Each tablet contains: Linagliptin 2.5 mg Hydrochloride Metformin 500 mg</p> <p>Package with 60 tablets.</p>	<p>Type 2 diabetes mellitus, in patients who do not respond to metformin alone, or as a substitute in those who are under treatment and achieve good control with the free combination of linagliptin and metformin.</p>	<p>Oral.</p> <p>Adults. 2.5/500mg every 12 hours.</p>
010.000.5741.00	<p>TABLET</p> <p>Each tablet contains: Linagliptin 2.5 mg Hydrochloride Metformin 850 mg.</p> <p>Package with 60 tablets.</p>		<p>2.5/850mg every 12 hours.</p>
010.000.5742.00	<p>TABLET</p> <p>Each tablet contains: Linagliptin 2.5 mg Hydrochloride Metformin 1000 mg</p> <p>Package with 60 tablets.</p>		<p>2.5/1000mg every 12 hours.</p>

#### Generalities

Linagliptin-metformin combines two antihyperglycemic drugs with complementary mechanisms of action to improve glycemic control in patients with type 2 diabetes: linagliptin, a dipeptidyl peptidase inhibitor 4 (DDP-4) and metformin hydrochloride, a member of the biguanide class.

#### Risk in Pregnancy

C

#### Adverse effects

The most frequently reported adverse reaction for linagliptin plus metformin was diarrhea (0.9%) with a rate comparable to that of metformin plus placebo (1.2%). Hypoglycemia may occur when Linagliptin-metformin is administered together with a sulfonylurea (1 case in 10 patients). In the analysis of pooled placebo-controlled trials, the overall incidence of adverse events in patients treated with placebo was similar to that of those treated with linagliptin 2.5 mg and metformin (50.6% and 47.8%). Treatment discontinuation due to adverse events was similar in patients receiving placebo and metformin and those receiving linagliptin and metformin (2.6% and 2.3%).

#### Contraindications and Precautions

Contraindications: Hypersensitivity to drugs. It should not be used in patients with Type 1 diabetes or for the treatment of diabetic ketoacidosis.

Precautions: Diabetic precoma, renal failure (creatinine clearance <60 mL/minute), acute conditions that may alter renal function: dehydration, severe infection, shock, intravascular administration of iodinated contrast, acute or chronic illness that can cause hypoxia: cardiac or respiratory failure, recent myocardial infarction, liver failure, acute alcoholism and alcoholism, lactic acidosis and hypoglycemia when Linagliptin-metformin is administered together with a sulfonylurea.

#### Interactions

Clinical data suggest that the risk of clinically significant interactions with co-administered medicinal products is low. Linagliptin had no clinically relevant effects on the pharmacokinetics of metformin, glibenclamide, simvastatin, pioglitazone, warfarin, digoxin or oral contraceptives, providing in vivo evidence of a low propensity to cause drug interactions with substrates of CYP3A4, CYP2C9, CYP2C8, glycoprotein P and the organic cationic transporter.

With metformin there is a greater risk of lactic acidosis in cases of acute alcoholism. Cationic agents that are eliminated by secretion from the renal tubules such as cimetidine may interact with metformin. Intravascular administration of iodinated contrast agents for radiological studies may cause insufficiency kidney, and risk of lactic acidosis; Therefore, it should be discontinued before or at the time of the study, and for the next 48 hours, and resume when kidney function has been reassessed and determined its normality.

## LIRAGLUTIDE

Clue	Description	Indications	Route of administration and dosage
010.000.5743.00	<p>INJECTABLE SOLUTION</p> <p>Each milliliter contains: Liraglutide (recombinant DNA) 6 mg.</p> <p>Package with 2 pens with a 3 mL cartridge.</p>	<p>Type 2 diabetes mellitus, in patients with failure to 2 oral agents, and who have a BMI &gt; 35</p> <p>Kg/m<sup>2</sup>, before the use of insulin.</p>	<p>Subcutaneous.</p> <p>Adults. Starting dose: 0.6 mg once daily for 7 days. Maintenance dose: 1.2 mg once daily.</p>

#### Generalities

Liraglutide is a GLP-1 analog with 97% sequence homology to human GLP-1 that binds to and activates the GLP-1 receptor. The GLP-1 receptor is the target of native GLP-1, an endogenous incretin hormone that enhances glucose-dependent insulin secretion in pancreatic beta cells. Unlike native GLP-1, liraglutide has a human pharmacokinetic and pharmacodynamic profile suitable for once-daily administration. Following subcutaneous administration, the delayed action profile is based on three mechanisms: self-association, resulting in slow absorption; binding to albumin and superior enzymatic stability with respect to dipeptidyl peptidase IV (DPP-IV) and the enzyme neutral endopeptidase (NEP), resulting in a prolonged plasma half-life.

#### Risk in Pregnancy

d

#### Adverse effects

Gastrointestinal disorders: nausea and diarrhea were very common, while vomiting, constipation, abdominal pain and dyspepsia were common. At the start of Liraglutide therapy, these gastrointestinal adverse reactions may occur more frequently. These reactions usually decrease after a few days or weeks of continued treatment. Headache and nasopharyngitis were also common.

In addition, hypoglycemia was found to be common, and very common if Liraglutide is used in combination with a sulfonylurea. Severe hypoglycemia has been observed primarily when combined with a sulfonylurea.

Very few cases of acute pancreatitis have been reported during long-term clinical studies with Liraglutide.

A causal relationship between Liraglutide and pancreatitis cannot be established or excluded.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. It should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Cautions: Liraglutide is not a substitute for insulin. The addition of liraglutide to the treatment of patients already using insulin has not been studied and therefore this use is not recommended. Experience in patients with New York Heart Association (NYHA) class I and II congestive heart failure is limited. There is no experience in patients with NYHA class III and IV congestive heart failure. Experience in patients with inflammatory bowel disease and diabetic gastroparesis is limited, therefore the use of Liraglutide in these patients is not recommended. The use of Liraglutide is associated with transient gastrointestinal adverse reactions, such as nausea, vomiting and diarrhea. Thyroid adverse events have been reported in clinical trials including increased blood calcitonin, goiter, and thyroid neoplasia, especially in patients with pre-existing thyroid disease. Patients receiving Liraglutide in combination with a sulfonylurea may be at increased risk of hypoglycemia. It is possible to reduce the risk of hypoglycemia by reducing the dose of sulfonylurea. Signs and symptoms of dehydration including renal insufficiency and acute renal failure have been reported in patients receiving Liraglutide. Patients receiving Liraglutide should be advised that there is a potential risk of dehydration related to gastrointestinal adverse effects and to take precautions to avoid fluid loss.

#### Interactions

*In vitro*, liraglutide has demonstrated a very low potential to be involved in pharmacokinetic interactions with other active substances related to cytochrome P450 and plasma protein binding. The slight delay in gastric emptying associated with liraglutide may influence the absorption of concomitant oral medications. Interaction studies have not demonstrated any clinically significant delay in absorption.

Few patients treated with liraglutide reported at least one episode of severe diarrhea. Diarrhea may influence the absorption of concomitant oral medications. No interaction studies have been performed with warfarin and other coumarin derivatives, so more frequent INR monitoring is recommended. No pharmacokinetic and pharmacodynamic interactions were observed between liraglutide and insulin detemir.

## METFORMIN/ GLIBENCLAMIDE

Code	Description	Indications	Route of administration and dosage
010.000.6273.00	<p>TABLET</p> <p>Each tablet contains: Metformin hydrochloride 500 mg. Glibenclamide 2.5 mg</p> <p>Package with 30 tablets.</p>	Diabetes mellitus type 2.	<p>Oral.</p> <p>Adults. 2 tablets per day during the main meal, without exceeding 2 g of metformin per day, later this daily dose may be reduced at the doctor's discretion.</p>

#### Generalities

Metformin. Biguanide that increases the peripheral effect of insulin and decreases gluconeogenesis. Glibenclamide.

Oral hypoglycemic agent derived from sulfonylureas that stimulates the activity of the beta cells of the pancreas, promoting insulin release of the

## Risk in Pregnancy

d

## Adverse effects

Hypoglycemia, urticaria, fatigue, weakness, headache, nausea, diarrhea, reactive hepatitis, hemolytic anemia and spinal hypoplasia, gastrointestinal intolerance, headache, transient skin allergies, metallic taste and lactic acidosis.

## Contraindications and Precautions

Glibenclamide. Contraindications: Hypersensitivity to the drug and sulfonamide derivatives. Diabetes mellitus type 1, kidney failure, pregnancy and lactation. Metformin. Contraindications: Hypersensitivity to the drug, type 1 diabetes mellitus, diabetic ketoacidosis, kidney failure, liver failure, heart or lung failure, severe malnutrition, chronic alcoholism and acute alcohol poisoning. Pregnancy and lactation.

## Interactions

Glibenclamide. Cyclophosphamide, oral anticoagulants, beta blockers and sulfonamides increase its hypoglycemic effect. Adrenergic corticosteroids, thiazide diuretics and furosemide decrease its hypoglycemic effect. A disulfiram-type reaction occurs with ethyl alcohol. Metformin. Decreases the absorption of vitamin B12 and folic acid. Sulfonylureas promote the hypoglycemic effect. Cimetidine increases the plasma concentration of metformin

**METFORMIN/GLIMEPIRYDE**

Clue	Description	Indications	Route of administration and dosage
010.000.6274.00	<p>TABLET</p> <p>Each tablet contains: Metformin hydrochloride 500 mg. Glimepiride 1 mg</p> <p>Package with 32 tablets.</p>	Diabetes mellitus type 2.	<p>Oral.</p> <p>Adults.</p> <p>1 tablet a day. Make gradual adjustments to determine the effective dose for each patient.</p>

## Generalities

Metformin. Biguanide that increases the peripheral effect of insulin and decreases gluconeogenesis. Glimepiride. It regulates insulin secretion by interacting with the ATP-sensitive potassium channel in pancreatic beta cells.

## Risk in Pregnancy

d

## Adverse effects

Hypoglycemia, urticaria, fatigue, weakness, headache, nausea, diarrhea, reactive hepatitis, hemolytic anemia and spinal hypoplasia, gastrointestinal intolerance, headache, transient skin allergies, metallic taste and lactic acidosis.

## Contraindications and Precautions

Hypersensitivity to the drug, type 1 diabetes mellitus, diabetic ketoacidosis, kidney failure, liver failure, heart or lung failure, severe malnutrition, chronic alcoholism and acute alcohol poisoning. Pregnancy and lactation

## Interactions

Metformin. Decreases the absorption of vitamin B12 and folic acid. Sulfonylureas promote the hypoglycemic effect. Cimetidine increases the plasma concentration of metformin

**METFORMIN/LINAGLIPTIN**

Clue	Description	Indications	Route of administration and dosage
010.000.5740.01	<p>TABLET</p> <p>Each tablet contains: Metformin Hydrochloride 500 mg Linagliptin 2.5 mg</p> <p>Package with 30 tablets.</p>	Diabetes mellitus type 2.	<p>Oral.</p> <p>2.5 mg linagliptin and 500 mg metformin twice daily.</p> <p>The maximum dose is 5 mg linagliptin and 2000 mg of metformin.</p>

## Generalities

Metformin. Biguanide that increases the peripheral effect of insulin and decreases gluconeogenesis. Linagliptin. DPP-4 enzyme inhibitor enzyme that participates in the inactivation of the incretin hormones GLP-1 and GIP, both incretin hormones participate in the physiological regulation of glucose taxis.

## Risk in Pregnancy

c

## Adverse effects

Hypoglycemia, urticaria, fatigue, weakness, headache, nausea, diarrhea, reactive hepatitis, hemolytic anemia and spinal hypoplasia, gastrointestinal intolerance, headache, transient skin allergies, metallic taste and lactic acidosis.

#### Contraindications and Precautions

Metformin. Contraindications: Hypersensitivity to the drug, type 1 diabetes mellitus, diabetic ketoacidosis, kidney failure, liver failure, heart or lung failure, severe malnutrition, chronic alcoholism and acute alcohol poisoning. Pregnancy and lactation

#### Interactions

Metformin. Decreases the absorption of vitamin B12 and folic acid. Sulfonylureas promote the hypoglycemic effect. Cimetidine increases the plasma concentration of metformin. Linagliptin should not be used in patients with type 1 diabetes, nor for the treatment of diabetic ketoacidosis.

### METHYLPREDNISOLONE

Clue	Description	Indications	Route of administration and dosage
010.000.0476.00	<p>INJECTABLE SOLUTION</p> <p>Each vial with lyophilisate contains</p> <p>Methylprednisolone sodium succinate equivalent to methylprednisolone. 500 mg</p> <p>Package with 50 vials and 50 ampoules with 8 mL of diluent.</p>	<p>Shock.</p> <p>Severe inflammation.</p> <p>Bronchial asthma crisis.</p>	<p>Intramuscular or slow intravenous.</p> <p>Adults:</p> <p>10 to 250 mg every 4 hours. Initial: 30 mg/kg. Maintenance: According to each particular case.</p> <p>Children:</p> <p>From 1 to 2 mg/kg/day, divide or fraction into four doses.</p>
010.000.3433.00	<p>INJECTABLE SUSPENSION</p> <p>Each mL contains: Acetate Methylprednisolone 40 mg.</p> <p>A vial with 2 mL.</p>	<p>Inflammatory arthropathies.</p> <p>Severe inflammation.</p>	<p>Intramuscular, intra-articular, intralesional.</p> <p>Adults:</p> <p>Intramuscular: 10 to 80 mg/day. Intra-articular: 40 to 80 mg every 1 to 5 weeks. Intralesional: 20 to 60 mg.</p>

#### Generalities

Glucocorticoid that inhibits phospholipase A2, therefore inhibiting the synthesis of prostaglandins, thromboxanes and leukotrienes.

#### Risk in Pregnancy

C

#### Adverse effects

Posterior subcapsular cataract, adrenal hypoplasia, Cushing's syndrome, obesity, osteoporosis, gastritis, superinfections, glaucoma, hyperosmolar coma, hyperglycemia, muscle catabolism, delayed healing, growth retardation and hydroelectrolyte disorders.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, active tuberculosis, diabetes mellitus, systemic infection, peptic ulcer, hypertensive crisis, liver and kidney failure and immunosuppression.

#### Interactions

Thiazide diuretics, furosemide and amphotericin B increase hypokalemia. Rifampicin, phenytoin and phenobarbital increase its hepatic biotransformation. Estrogens decrease its biotransformation. Antacids decrease its absorption. With digitalis the risk of digitalis poisoning increases. Increases the biotransformation of isoniazid.

### OCTREOTIDE

Clue	Description	Indications	Route of administration and dosage
010.000.5171.00	<p>INJECTABLE SUSPENSION</p> <p>Each vial contains: Octreotide acetate equivalent to 20 mg of octreotide.</p> <p>Container with a vial and two vials with diluent.</p>	<p>Acromegaly.</p> <p>Functional gastro-pancreatic endocrine tumors.</p>	<p>Deep intramuscular.</p> <p>Adults:</p> <p>10-30 mg every 4 weeks.</p>

010.000.5171.01	Package with a vial and a syringe prefilled with 2.5 mL of diluent.		
010.000.5171.02	Container with a vial and a syringe prefilled with 2 mL of diluent.		

#### Generalities

Synthetic analogue of somatostatin that acts as a potent inhibitor of some hormones, especially growth hormone, insulin and glucagon.

#### Risk in Pregnancy

x

#### Adverse effects

Pain, paresthesia, redness at the application site. Anorexia, nausea, vomiting, crampy abdominal pain, diarrhea, steatorrhea, hypoglycemia or hyperglycemia. Prolonged use may result in gallstone formation. Transient hair loss has rarely been reported. Acute hepatitis without cholestasis during the first hours or days of treatment.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.  
Precautions: In hepatitis and diabetes mellitus.

#### Interactions

It may decrease the plasma concentration of cyclosporine and lead to transplant rejection. Concomitant administration of octreotide with bromocriptine increases the availability of bromocriptine.

## PARICALCITOL

Clue	Description	Indications	Route of administration and dosage
010.000.1100.00	<p>INJECTABLE SOLUTION</p> <p>Each vial or vial contains:</p> <p>Paricalcitol 5µg</p> <p>Container with 5 vials or vials with 1mL.</p>	Prevention and treatment of hyperparathyroidism secondary to chronic renal failure resistant to calcitriol.	<p>Intravenous.</p> <p>From 0.04 µg/kg to 0.1 µg/kg of body weight, every third day.</p>
010.000.1101.00	<p>CAPSULE</p> <p>Each capsule contains:</p> <p>Paricalcitol 2 µg.</p> <p>Container with 30 capsules.</p>		<p>Oral.</p> <p>Adults and people over 18 years of age:</p> <p>Initial dose.</p>
010.000.1102.00	<p>CAPSULE</p> <p>Each capsule contains:</p> <p>Paricalcitol 4 µg.</p> <p>Container with 30 capsules.</p>		<p>Based on basal levels of Intact Parathyroid Hormone (HPTi).</p> <p>PHT &lt; 500 pg/mL; 2 µg three times a week.</p> <p>HPTi ≥ 500 pg/mL; 4 µg three times a day week.</p>

#### Generalities

Synthetic analogue of calcitriol, metabolically active form of vitamin D. Vitamin D and paricalcitol have been shown to reduce parathyroid hormone levels and normalize calcium and phosphorus homeostasis.

#### Risk in Pregnancy

c

#### Adverse effects

Chills, fever, cold, sepsis, palpitations, xerostomia, gastrointestinal bleeding, nausea, vomiting, edema, lightheadedness, pneumonia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.  
Precautions: Digitalis toxicity is enhanced by hypercalcemia from any cause. Lactation.

#### Interactions

Caution should be used when dosing paricalcitol with ketoconazole and other P450 3rd inhibitors.

**PIOGLITAZONE**

Clue	Description	Indications	Route of administration and dosage
010.000.4149.00	TABLET  Each tablet contains: Pioglitazone hydrochloride equivalent to 15 mg of pioglitazone.  Package with 7 tablets.	Diabetes mellitus type 2.	Oral.  Adults:  15 to 30 mg every 24 hours.

**Generalities**

Thiazolidinedione that improves insulin sensitivity in liver, fat and skeletal muscle cells through specific activation of the peroxisome proliferator-activated receptor gamma and stimulates the expression of genes that control lipids and glucose.

**Risk in Pregnancy**

x

**Adverse effects**

Respiratory tract infection, headache, sinusitis, myalgia, dental disorders, pharyngitis, anemia and bimalleolar edema.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug, pregnancy and lactation, liver and heart failure.  
Precautions: Premenopausal women may increase the risk of pregnancy.

**Interactions**

Inhibits the action of contraceptives. Ketoconazole inhibits its metabolism.

**PRAVASTATIN**

Clue	Description	Indications	Route of administration and dosage
010.000.0657.00	TABLET  Each tablet contains: Pravastatin sodium 10 mg.  Package with 30 tablets.	Hypercholesterolemia.	Oral.  Adults:  10 to 40 mg every 24 hours, preferably at night.

**Generalities**

It inhibits hepatic cholesterol synthesis and increases LDL catabolism.

**Risk in Pregnancy**

x

**Adverse effects**

Muscle pain, nausea, vomiting, diarrhea, constipation, abdominal pain, headache, dizziness and elevation of liver transaminases.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug, liver dysfunction, pregnancy and lactation.

**Interactions**

Cyclosporine increases plasma levels of pravastatin.

**PREDNISOLONE**

Clue	Description	Indications	Route of administration and dosage
	ORAL SOLUTION  Each 100 mL contains: Prednisolone sodium phosphate equivalent to 100 mg of prednisolone.	Inflammatory and autoimmune diseases.  Bronchial asthma.  Diseases	Oral.  Adults and children:  Initial dose: 1-2 mg/kg body weight/day.  Maintenance dose: 0.1-0.5 mg/kg



010.000.2482.00	Container with 100 mL bottle and glass 20 mL graduated.	neoplastic.	body weight/day.
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#### Generalities

Anti-inflammatory and glucocorticoid action greater than hydrocortisone, with a significant decrease in mineralocorticoid action.

#### Risk in Pregnancy

c

#### Adverse effects

Hirsutism, lunar facies, skin striae, acne, hyperglycemia, systemic arterial hypertension, increased susceptibility to infections, peptic ulcer, myopathy, behavioral disorders, posterior subcapsular cataract, osteoporosis, obesity and adrenal suppression.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug or prednisone and systemic infectious processes.

#### Interactions

Rifampicin, barbiturates and phenytoin shorten the elimination half-life. Oral contraceptives can prolong their half-life.

## ROSIGLITAZONE

Clue	Description	Indications	Route of administration and dosage
010.000.4150.00 010.000.4150.01	TABLET  Each tablet contains: Rosiglitazone maleate equivalent to 4 mg rosiglitazone  Package with 14 tablets. Package with 28 tablets.	Diabetes mellitus type 2.	Oral.  Adults:  4 mg every 24 hours, you can increase the dose to one tablet every 12 hours.

#### Generalities

It is an agonist of the peroxisomal proliferation activator receptor gamma that interacts in the cell nucleus, activating the insulin response on glucose metabolism. Reduces insulin resistance and improves glucose uptake.

#### Risk in Pregnancy

d

#### Adverse effects

Upper respiratory tract infection, elevation of LDL cholesterol, headache, back pain and fatigue.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.  
Precautions: Heart failure.

#### Interactions

None of clinical importance.

## ROSUVASTATIN

Clue	Description	Indications	Route of administration and dosage
010.000.4023.00	TABLET  Each tablet contains: Rosuvastatin calcium equivalent to 10 mg rosuvastatin  Package with 30 tablets.  Each tablet contains:	Hypercholesterolemia.  Hyperlipidemia.	Oral.  Adults:  10 or 20 mg every 24 hours, at night.

010.000.6277.00	Rosuvastatin calcium equivalent to 20 mg rosuvastatin Package with 30 tablets.		
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#### Generalities

Rosuvastatin has a first-pass effect on the liver, which is the primary site of cholesterol synthesis and LDL-C clearance. Rosuvastatin is 90% bound to plasma proteins, mainly albumin. The parent compound accounts for more than 90% of the circulating HMG CoA reductase inhibitory activity.

#### Risk in Pregnancy

c

#### Adverse effects

Headache, myalgia, asthenia, constipation, dizziness, nausea, abdominal pain, pruritus, rash and urticaria.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the medication.

Precautions: In patients who consume excessive amounts of alcohol, or have a history of liver disease.

#### Interactions

Antacids reduce plasma concentrations of rosuvastatin and erythromycin increases them. Rosuvastatin increases plasma digoxin concentrations. Concomitant use with gemfibrosil increases the risk of Cmax and AUC (0-t) of rosuvastatin.

## SIMVASTATIN

Clue	Description	Indications	Route of administration and dosage
010.000.4124.00	TABLET Each tablet contains: Simvastatin 20 mg. Package with 14 tablets.	Hypercholesterolemia.	Oral. Adults: 20-40 mg every 24 hours, preferably at night.
010.000.4124.01	Package with 30 tablets.		

#### Generalities

Competitive inhibitor of HMG-CoA reductase, with greater effect in reducing LDL.

#### Risk in Pregnancy

x

#### Adverse effects

Muscle pain, nausea, vomiting, diarrhea, constipation, abdominal pain, headache, dizziness and elevation of liver transaminases.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, pregnancy, lactation and active liver disease.

Precautions: Therapeutic with fibrates and niacin.

#### Interactions

Cimetidine, ranitidine and omeprazole increase their bioavailability. Rifampin decreases it.

## SITAGLIPTIN

Clue	Description	Indications	Route of administration and dosage
010.000.4152.00	COMPRESSED Each tablet contains: Sitagliptin phosphate monohydrate equivalent to 100 mg of sitagliptin. Package with 14 tablets.	Diabetes mellitus type 2.	Oral. Adults: 50 mg every 12 hours or 100 mg every 2 hours as monotherapy or in combination treatment with metformin or glitazones.
010.000.4152.01	Package with 28 tablets.		
	COMPRESSED		

010.000.4153.00 010.000.4153.01	Each tablet contains: Sitagliptin phosphate monohydrate equivalent to 50 mg sitagliptin  Package with 14 tablets. Package with 28 tablets.
010.000.7120.00 010.000.7120.01	TABLET  Each tablet contains: Hydrochloride Sitagliptin Monohydrate equivalent to 100 mg of Sitagliptin  Container with 14 tablets Container with 28 tablets
010.000.7121.00 010.000.7121.01	TABLET  Each tablet contains: Hydrochloride Sitagliptin Monohydrate equivalent to 50 mg of Sitagliptin  Container with 14 tablets Container with 28 tablets

**Generalities**

It is a member of a class of antihyperglycemic agents called dipeptidylpeptidase 4 (DPP-4) inhibitors, which improve glycemic control in patients with type 2 diabetes by increasing concentrations of incretin hormones.

**Risk in Pregnancy**

d

**Adverse effects**

Abdominal pain, nausea, vomiting and diarrhea.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug.

Precautions: Dosage adjustment is recommended in patients with moderate or severe renal impairment and in patients with end-stage renal disease requiring hemodialysis.

**Interactions**

The area under the curve and maximum plasma concentration (AUC and C<sub>max</sub>) increased slightly by 11% and 18%, respectively, when sitagliptin and digoxin were co-administered. Besides; The AUC and C<sub>max</sub> of sitagliptin increased by approximately 29% and 68%, respectively, when single oral doses of sitagliptin 100 mg and cyclosporine 600 mg were coadministered.

**SITAGLIPTIN, METFORMIN**

Clue	Description	Indications	Route of administration and dosage
010.000.5705.00 010.000.5705.01	TABLET or TABLET  Each tablet contains: Sitagliptin phosphate monohydrate ... Hydrochloride of sitagliptin Monohydrate  equivalent to 50 mg sitagliptin Metformin hydrochloride 500 mg.  Package with 28 tablets or tablets.  Package with 56 tablets or tablets.	Treatment of type 2 diabetes mellitus in adult patients with failure in glycemic control with metformin or sitagliptin monotherapy or patients at with high risk of with hypoglycemia, adult patients who are currently stable on metformin plus sitagliptin treatment. ... in  with	Oral. Adults: One tablet or tablet every 12 hours.
	TABLET or TABLET  Each tablet contains: Sitagliptin Phosphate Monohydrate		

<p>010.000.5703.00</p> <p>010.000.5703.01</p>	<p>Hydrochloride of sitagliptin Monohydrate</p> <p>equivalent to 50 mg sitagliptin Metformin hydrochloride 850 mg.</p> <p>Package with 28 tablets or tablets.</p> <p>Package with 56 tablets or tablets.</p>		
<p>010.000.5704.00</p>	<p>TABLET or TABLET</p> <p>Each tablet contains: Sitagliptin Phosphate Monohydrate</p> <p>Hydrochloride of sitagliptin Monohydrate</p> <p>equivalent to 50 mg sitagliptin Metformin hydrochloride 1000 mg.</p> <p>Package with 56 tablets or tablets.</p>		

#### Generalities

The mechanism of action of the combination of sitagliptin and metformin in the same tablet is characterized by the fact that it acts on the three main defects associated with type 2 diabetes: the deficit in insulin production by beta cells, insulin resistance and excess glucose production by the liver. The sitagliptin component of the tablet increases the concentration of the active forms of incretins, thereby enhancing a natural process in the body that increases the synthesis and release of insulin by pancreatic cells, and decreases the secretion of glucagon by alpha cells. of the pancreas, thereby reducing glucose production by the liver. Metformin, the other component of the tablet, is one of the pillars of diabetes treatment; it acts on insulin resistance, increasing the uptake and use of glucose. Metformin also reduces glucose production by the liver, in a complementary way to sitagliptin.

#### Risk in Pregnancy

c

#### Adverse effects

Diarrhea, nausea, dyspepsia, flatulence, vomiting, headache, hypoglycemia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to drugs. Nephropathy or renal dysfunction, acute myocardial infarction or septicemia, acute or chronic metabolic acidosis.

Precautions: Sitagliptin/metformin should not be used in patients with type 1 DM or to treat diabetic ketoacidosis. Monitor kidney function. Metformin should not be used in patients with moderate to moderate renal impairment. severe due to the risk of lactic acidosis.

#### Interactions

Pharmacokinetic interaction studies have not been done with Sitagliptin, metformin, but with their individual components, sitagliptin and metformin.

Sitagliptin: In drug interaction studies, sitagliptin had no clinically important effects on the pharmacokinetics of the following medications: metformin, rosiglitazone, glyburide, simvastatin, warfarin and oral contraceptives. According to these data, sitagliptin does not inhibit the cytochrome P-450 isoenzymes CYP3A4, 2C8 and 2C9.

Furosemide: A study on the interaction of single doses of metformin and furosemide in healthy subjects showed that coadministration affected the pharmacokinetic parameters of both compounds. Furosemide increased the plasma and blood C<sub>max</sub> by 22% and the blood AUC of metformin by 15%, without any significant change in its renal clearance. When co-administered with metformin, the C<sub>max</sub> and AUC of furosemide were 31 and 12% lower, respectively, than when administered alone, and its terminal half-life was decreased by 32%, without any significant change in its renal clearance. There is no information available about the interaction of metformin and furosemide when coadministered for a long time.

Nifedipine: A single-dose interaction study of metformin and nifedipine in healthy subjects demonstrated that coadministration of nifedipine increased the C<sub>max</sub> and AUC of metformin by 20% and the amount of metformin excreted in the urine by 9%. Its T<sub>max</sub> and half-life were unchanged. Nifedipine increases the absorption of

metformin, and this had minimal effects on nifedipine.

Cationic medications: Cationic medications (such as amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion can theoretically interact with metformin by competing with it for tubular transport systems. common kidney.

Certain medications tend to cause hyperglycemia and may impede blood glucose control. These medications include thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blockers, and isoniazid. When any of these medications are administered to a patient who is taking Sitagliptin, metformin, they should be closely monitored to ensure good blood glucose control.

## SOMATROPIN

Clue	Description	Indications	Route of administration and dosage
010.000.5163.00	<p>INJECTABLE SOLUTION</p> <p>Each vial with lyophilisate contains:</p> <p>Biosynthetic somatropin 1.33 mg equivalent to 4 IU.</p> <p>Container with vial and vial or vial with 1 or 2 mL of diluent.</p>	<p>Poor growth due to inadequate growth hormone secretion</p> <p>endogenous.</p>	<p>Intramuscular or subcutaneous.</p> <p>Children:</p> <p>0.16 IU/kg, three times a week. Do not administer more than 12 IU/m<sup>2</sup> of body surface area per week.</p>
010.000.5167.00 010.000.5167.01	<p>INJECTABLE SOLUTION</p> <p>Each cartridge with two compartments, one with lyophilisate, contains:</p> <p>Somatropin 5.3 mg equivalent to 16 IU and another with the diluent.</p> <p>Package with a cartridge with two compartments, one with lyophilisate and the other with the diluent.</p> <p>Container with vial with lyophilisate and vial with 2 mL of diluent.</p>		<p>Subcutaneous or intramuscular.</p> <p>Adults:</p> <p>0.018 to 0.036 IU/kg body weight/day.</p> <p>Children:</p> <p>2.1 to 3 IU/ m<sup>2</sup> of body surface/day or 0.7 to 1.0 mg/ m<sup>2</sup> of body surface area / day.</p>
010.000.5174.01 010.000.5174.02	<p>INJECTABLE SOLUTION</p> <p>Each vial with lyophilisate contains:</p> <p>Biosynthetic somatropin 8 mg equivalent to 24 IU.</p> <p>Package with a vial with lyophilisate and multidose autoinjector.</p> <p>Package with a vial with lyophilisate and a cartridge (prefilled syringe) with diluent.</p>	<p>Poor growth due to inadequate secretion of endogenous growth hormone.</p> <p>Growth hormone deficiency in adults.</p>	<p>Subcutaneous (using hidden needle autoinjector).</p> <p>Children:</p> <p>0.18 to 0.25 mg/kg body weight (0.54 to 0.80 IU/kg body weight) per week. It is recommended to divide into three to six applications.</p> <p>Adults:</p> <p>0.08 mg/kg body weight (0.125 IU/kg) per week, which can be increased to 0.16 mg/kg (0.25 IU/kg body weight).</p> <p>In both cases it is recommended to divide it into six or seven applications per week.</p>
010.000.5694.01	<p>INJECTABLE SOLUTION</p> <p>Each cartridge with two compartments, one with lyophilisate, contains:</p> <p>Somatropin 13.80 mg equivalent to 36 IU and another with the 1 mL diluent.</p> <p>Package with a cartridge prefilled with 1.5 mL to be administered in an autoinjector device.</p>	<p>Treatment of children with growth hormone deficiency.</p>	<p>Subcutaneous or intramuscular.</p> <p>Children:</p> <p>2.1 to 3.0 IU/m<sup>2</sup> body surface area/day.</p> <p>0.7 to 1.0 mg/m<sup>2</sup> body surface area/day</p>
010.000.5750.00	<p>INJECTABLE SOLUTION</p> <p>Each milliliter contains:</p> <p>Somatropin 3.30 mg.</p> <p>Package with a 1.5 mL (5 mg/1.5 mL) pre-filled pen.</p>	<p>Growth hormone secretion deficiency.</p>	<p>Subcutaneous.</p> <p>Children:</p> <p>25 to 35 <math>\mu</math>g /Kg of body weight/day or 0.7 to 1.0 mg/m<sup>2</sup> body surface area/day.</p>
	INJECTABLE SOLUTION		

010.000.5751.00	Each milliliter contains: Somatropin 6.70 mg  Package with a 1.5 mL (10 mg/1.5 mL) pre-filled pen.		
010.000.5752.00	INJECTABLE SOLUTION  Each milliliter contains: Somatropin 10.0 mg.  Package with a 1.5 mL pre-filled pen (15 mg/1.5 mL).		
010.000.5754.00	INJECTABLE SOLUTION  Each milliliter contains: Recombinant somatropin 6,666 mg.  Container with cartridge with 1.5 mL. [(10 mg/1.5 mL) equivalent to 30 IU] for multidose injector device.		

#### Generalities

Growth hormone, with anabolic action.

#### Risk in Pregnancy

c

#### Adverse effects

Hypersensitivity, hypothyroidism, hyperglycemia, benign intracranial hypertension, otitis media. Very common: In adults peripheral edema. Common: In adults, headache, paresthesia, arthralgia, myalgia, and joint stiffness. Uncommon: In adults type 2 diabetes mellitus, carpal tunnel syndrome, pruritus, muscle stiffness and pain at the injection site. In children Headache, injection site pain and injection site reaction NOS. Rare: In children NOS rash, arthralgia, myalgia and peripheral edema.

#### Contraindications and Precautions

Contraindications: Patients who present evidence of tumor activity, neoplasms must be inactivated and antitumor therapy must be completed before instituting treatment, pregnancy and lactation, promotion of longitudinal growth in children with closed epiphysis, patients with acute critical illness, patients suffering complications after open heart surgery, patients after abdominal surgery, multiple trauma respiratory complications or similar conditions. Hypersensitivity to some of the components of the formula, patients with Prader-Willi Syndrome who have severe obesity or respiratory deficiency. Diabetes with active proliferative retinopathy or severe non-proliferative retinopathy. Precautions: Do not exceed the maximum recommended daily dose; stimulation of longitudinal growth in children can be expected until the epiphyseal discs are closed.

Chronic renal failure: During treatment, uremia should be conservatively managed with regular medication, and dialysis should be maintained if necessary. Renal function should be monitored to detect an excessive decrease or increase in the glomerular filtration rate (which could imply hyperfiltration). Neoplasms: Somatropin treatment should be discontinued in case of any development or recurrence of cancer. There is no evidence of an increased risk of new primary cancers in children or adults treated with somatropin. In patients in complete remission of tumors or cancer, somatropin therapy has not been associated with an increase in the relapse rate. Benign intracranial hypertension: Very rare cases have been reported; if so, treatment should be suspended. Thyroid function: Hypothyroidism interferes with the response to somatropin treatment, patients should undergo regular testing regarding their thyroid function and should receive thyroid hormone replacement therapy when indicated.

#### Interactions

Concomitant treatment with glucocorticoids inhibits growth-promoting effects. In adults with growth hormone deficiency, it suggests that the administration of somatropin may increase the clearance of compounds known to be metabolized by cytochrome P450 isoenzymes, such as sex steroids, corticosteroids, anticonvulsants, and cyclosporines. In patients treated with insulin, an adjustment of the insulin dose may be necessary after initiating treatment with somatropin.

## TALIGLUCERASE ALFA

Clue	Description	Indications	Route of administration and dosage
010.000.5614.00	INJECTABLE SOLUTION  Each vial with lyophilisate contains:  Taliglucerase alfa 200 U.  Container with vial bottle with lyophilized powder.	Enzyme replacement therapy for the treatment of Gaucher disease type 1 for adults and pediatric patients.	Intravenous.  Adults and pediatric patients: 30 to 60 U/Kg of body weight, once every two weeks.

### Generalities

Enzyme replacement therapy is the standard treatment for GD and is based on the premise of administering recombinant  $\gamma$ -GCD to compensate for  $\gamma$ -GCD deficiency in patients with GD.

### Risk in Pregnancy

b

### Adverse effects

The most common adverse reactions are infusion-related reactions: headache, pruritus, nausea, peripheral edema, throat irritation, erythema and flushing.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, to carrots, and children under 18 years of age.  
Precautions: Response to antibodies.

### Interactions

No pharmacodynamic interaction studies with other drugs were performed.

## TERIPARATIDE

Clue	Description	Indications	Route of administration and dosage
010.000.4174.00	<p>INJECTABLE SOLUTION</p> <p>Each milliliter contains: Teriparatide 250 <math>\mu</math>g.</p> <p>Pen container with assembled 2.4 mL cartridge.</p>	<p>Women and men with osteoporosis with previous hip or spine fractures, high risk of new fractures and who have not responded to treatment with calcitriol or bisphosphonates.</p>	<p>Subcutaneous.</p> <p>Adults: 20 <math>\mu</math>g every 24 hours.</p>

### Generalities

Parathyroid hormone that has an identical sequence with the first 34 amino acids of the N terminus of the 84-amino acid natural human parathyroid hormone. Primary regulator of calcium and phosphate metabolism in bones and kidneys.

### Risk in Pregnancy

c

### Adverse effects

Nausea, arthralgia, leg cramps, dizziness, depression, insomnia, vertigo.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the medication.  
Precautions: History of radiotherapy.

### Interactions

None of clinical importance. Concomitant administration with Raloxifene did not alter the expected response with Teriparatide and did not modify the adverse reactions.

## TESTOSTERONE

Clue	Description	Indications	Route of administration and dosage
010.000.1061.00	<p>INJECTABLE SOLUTION</p> <p>Each vial contains: Testosterone enanthate 250 mg.</p> <p>Vial container with 1 mL.</p>	<p>Hypogonadism male.</p> <p>Breast cancer.</p>	<p>Intramuscular.</p> <p>Adults: Hypogonadism: 50 to 400 mg every 2 to 4 weeks. Delayed puberty: 25 to 200 mg every 2 to 4 weeks for 6 months.</p>
010.000.5164.00 010.000.5164.01	<p>CAPSULE</p> <p>Each capsule contains: Testosterone undecanoate 40 mg.</p> <p>Container with 30 capsules. Container with 60 capsules.</p>	<p>Hypogonadism male.</p>	<p>Oral.</p> <p>Adults: Start: 120 to 160 mg/day for 3 weeks. Maintenance: 40 to 120 mg/day. Adjust the dose according to the patient's response.</p>

### Generalities

Androgen that promotes the growth and development of sexual organs and secondary male characteristics.

Risk in Pregnancy

x

Adverse effects

Fluid retention, hepatotoxicity, acne, hair loss, increased muscle mass, nausea, vomiting, urticaria, anaphylactic reactions and leukopenia.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, prostate cancer, breast cancer in men, pregnancy and lactation.

Interactions

None of clinical importance.

**THIAMAZOL**

Clue	Description	Indications	Route of administration and dosage
010.000.1022.00	TABLET  Each tablet contains: Thiamazol 5 mg.  Package with 20 tablets.	Hyperthyroidism.	Oral.  Adults and children: Initial dose of 5 to 20 mg/ every 8 hours. If hypothyroidism occurs, the dose can be reduced until euthyroidism is achieved (usually reduced to one-third of the initial dose).

Generalities

Inhibits the synthesis of thyroid hormone.

Risk in Pregnancy

d

Adverse effects

Lymphadenopathy, leukopenia, agranulocytosis, aplastic anemia, diarrhea, vomiting, jaundice, headache and vertigo.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, hypothyroidism and breastfeeding.  
 Precautions: Pregnancy.

Interactions

None of clinical importance.

**THYROXINE - TRIYODOTYRONINE**

Clue	Description	Indications	Route of administration and dosage
010.000.1005.00	TABLET  Each tablet contains: Thyroxine 100 µg. Triiodothyronine 20 µg.  Package with 50 tablets.	Hypothyroidism.	Oral.  Adults: Start: 50 µg of thyroxine and 10 µg of triiodothyronine per day. Subsequently increase the dose (half a tablet) every two weeks until the therapeutic effect is obtained.

Generalities

Thyroid hormones stimulate brain and body development, heat production and promote the utilization of proteins, carbohydrates, lipids, vitamins, electrolytes and water.

Risk in Pregnancy

TO

Adverse effects

Tachycardia, angina pectoris, nervousness, insomnia, headache, weight loss, diarrhea, cramps.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, recent myocardial infarction, thyrotoxicosis.



## Interactions

Increases insulin and oral hypoglycemic requirements. Reduces the effects of oral anticoagulants.

**VASOPRESSIN**

Clue	Description	Indications	Route of administration and dosage
010.000.4154.00	INJECTABLE SOLUTION  Each vial contains: Vasopressin 20 IU.  Container with a vial.	Diabetes insipidus nephrogenic and non-psychogenic.	Intramuscular or subcutaneous.  Adults: 5 to 10 IU every 8 to 12 hours. Maximum 60 IU/day.  Children: 2.5 to 10 IU every 8 to 12 hours.

## Generalities

It increases the permeability of the convoluted tubules and promotes water reabsorption, producing an increase in urine osmolarity and a decrease in urine volume.

## Risk in Pregnancy

b

## Adverse effects

Angioneurotic edema, diarrhea, vomiting, angina pectoris, systemic arterial hypertension and arrhythmias.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Chronic nephritis, epilepsy, bronchial asthma, heart failure, coronary heart disease and liver disease.

## Interactions

Carbamazepine, chlorpropamide and clofibrate may increase their antidiuretic effect. Lithium, adrenergics, tetracyclines, heparins and alcohol decrease its antidiuretic effect.

**VELAGLUCERase ALFA**

Clue	Description	Indications	Route of administration and dosage
010.000.5615.00	INJECTABLE SOLUTION  Each vial with lyophilisate contains:  Velagluclerase alfa 400 U.  Container with vial bottle with freeze-dried.	replacement therapy enzymatic for the treatment of Gaucher disease type 1.	Intravenous.  Children, adolescents and adults. 60 U/Kg of body weight, every two weeks. Adjust the dose according to the patient's response to enzyme replacement therapy.  Reconstitute with 4.3 mL of sterile distilled water. Once reconstituted, the solution contains:  100 U/mL of Velagluclerase alfa in an extraction volume of 4.0 mL.  Dilute in 100 mL of 0.9% physiological sodium chloride solution. Administer the solution for 60 minutes.

## Generalities

Specific glucocerebrosidase hydrolytic lysosome enzyme obtained by gene activation technology in a human cell line. Glycoprotein that catalyzes the hydrolysis of the glycolipid glucocerebrosidase to glucose and ceramide in the lysosome, thereby reducing the amount of accumulated glucocerebrosidase and increasing Hb concentration and platelet count, and reducing liver and spleen volumes.

## Risk in Pregnancy

b

## Adverse effects

Headache, dizziness, bone and back pain, arthralgia, perfus-related reaction, asthenia/fatigue, pyrexia/increased body temperature, hypersensitivity, tachycardia, hyper and hypotension, flushing, abdominal pain/pain in upper abdomen, nausea, rash, urticaria, prolongation of activated partial thromboplastin time.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Allergic hypersensitivity reactions.

#### Interactions

No formal interaction studies have been performed.

## VILDAGLIPTIN, METFORMIN

Code	Description	Indications	Route of administration and dosage
010.000.5700.00	COMPRESSED Each tablet contains: Vildagliptin 50 mg. Metformin hydrochloride 500 mg. Package with 30 tablets.	Diabetes Treatment Mellitus Type 2 in patients in whom there is weight gain that causes problems, when thiazolidinediones are contraindicated, or if the patient had a poor response or intolerance to them in the past, or in patients who are currently stable on treatment with	Oral. Adults: One tablet every 12 hours.
010.000.5701.00	COMPRESSED Each tablet contains: Vildagliptin 50 mg. Metformin hydrochloride 850 mg. Package with 30 tablets.	metformin + vildagliptin	
010.000.5702.00	COMPRESSED Each tablet contains: Vildagliptin 50 mg. Metformin hydrochloride 1000 mg. Package with 30 tablets.		

#### Generalities

Vildagliptin acts by inhibiting the action of the enzyme dipeptidyl-peptidase 4 (DPP-4), which increases the levels of incretin hormones -GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulinotropic peptide)-stimulating insulin secretion and regulating glucagon secretion, depending on glucose concentrations. For its part, Metformin inhibits gluconeogenesis and glycogenolysis, reduces hepatic glucose production, increases insulin sensitivity, improves peripheral glucose uptake and utilization, and delays intestinal glucose absorption.

#### Risk in Pregnancy

c

#### Adverse effects

Angioedema, liver dysfunction, dizziness, headaches, constipation and peripheral edema, nausea, vomiting, diarrhea, abdominal pain, loss of appetite, decreased absorption of vitamin B12, lactic acidosis, hepatitis, skin reactions such as erythema, pruritus and urticaria, shaking.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to drugs.

Precautions: Renal failure or nephropathy, congestive heart failure, acute or chronic metabolic acidosis, such as diabetic ketoacidosis with or without coma; Treatment should be temporarily discontinued in patients undergoing radiological studies in which iodinated contrast media are administered intramuscularly.

#### Interactions

Interactions with Vildagliptin: reduced drug interaction capacity; no clinically significant interaction with other oral antidiabetic agents (glibenclamide, pioglitazone, metformin), amLodipine, digoxin, ramipril, simvastatin, valsartan or warfarin, when these drugs are co-administered with vildagliptin. Interactions with metformine hydrochloride: furosemide, nifedipine, cationic substances; substances that tend to produce hyperglycemia, alcohol.

