

Update date: February 1, 2024

## Group No. 13: Pulmonology

**ACETYLCYSTEINE**

Clue	Description	Indications	Route of administration and dosage
010.000.4326.00	20% SOLUTION  Each vial contains: Acetylcysteine 400 mg.  Package with 5 vials with 2 mL (200 mg/mL).	Processes bronchopulmonary with viscous hypersecretion and mucostasis.	Nasal nebulization.  Adults and children over 7 years old: 600 to 1000 mg/day, divided every 8 hours.  Children from 2 to 7 years: 300 mg/day, divided every 8 hours.  Children up to 2 years: 200 mg/day, divided every 12 hours.
		Paracetamol poisoning. by	Oral  Adults and children:  Starting dose, 140 mg/kg body weight; then 70 mg/kg body weight, each 4 hours, up to 18 doses or a period of 72 hours.

## Generalities

Sulphurous amino acid with fluidizing action on mucous and mucopurulent secretions in respiratory processes that cause hypersecretion and mucostasis.

## Risk in Pregnancy

c

## Adverse effects

Immediate hypersensitivity reactions, nausea, vomiting, headache, chills, fever, rhinorrhea, diarrhea, bronchospasm.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, diabetes mellitus, gastroduodenal ulcer. Precautions: Asthma, use of tetracyclines.

## Interactions

Antibiotics such as amphotericin, ampicillin sodium, erythromycin lactobionate and some tetracyclines are physically incompatible or can be inactivated by mixing with acetylcysteine.

**AMBROXOL**

Clue	Description	Indications	Route of administration and dosage
010.000.2462.00	COMPRESSED  Each tablet contains: Hydrochloride ambroxol 30 mg.  Package with 20 tablets.	Bronchitis.	Oral.  Adults: 30 mg every 8 hours.  Children: Children under two years: 2.5 mL every 12 hours.  Children over five years: 5 mL every 8 hours.
	SOLUTION  Each 100 mL contains: Hydrochloride ambroxol 300 mg.  Container with 120 mL and dispenser.		

## Generalities

It acts on bronchial secretions by fragmenting and breaking up their filamentous organization.

## Risk in Pregnancy

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## Adverse effects

Nausea, vomiting, diarrhea, headache, allergic reactions.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, peptic ulcer.

## Interactions

None of clinical importance.

## AMINOPHYLLINE

Clue	Description	Indications	Route of administration and dosage
010.000.0426.00	INJECTABLE SOLUTION  Each vial contains: Aminophylline 250 mg.  Container with 5 vials of 10 mL.	Bronchial asthma. Bronchospasm.	Intravenous.  Adults:  Initial: 6 mg/kg body weight, for 20 to 30 minutes. Maintenance: 0.4 to 0.9 mg/kg body weight/hour.  Children:  From 6 months to 9 years. Initial: 1.2 mg/kg body weight/hour, per 12 hours. Maintenance: 1 mg/kg body weight/hour.  From 9 to 16 years old. Initial: 1 mg/kg body weight/hour, per 12 hours. Maintenance: body/ 0.8 mg/kg weight hour.  Administer diluted in intravenous solutions packaged in glass bottles.

## Generalities

It inhibits phosphodiesterase, producing relaxation of smooth muscle, especially bronchial muscle.

Risk in Pregnancy  c

## Adverse effects

Nausea, vomiting, diarrhea, irritability, insomnia, headache, seizures, arrhythmia, tachycardia, hypotension.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, peptic ulcer, arrhythmias and heart failure.

## Interactions

Barbiturates, phenytoin, and rifampicin decrease theophylline concentrations. The influenza virus vaccine, hormonal contraceptives, and erythromycin raise blood levels of theophylline. Paradoxical bronchospasm with  $\beta$  blockers.

## BECLOMETHASONE, DIPROPIONATE

Clue	Description	Indications	Route of administration and dosage
010.000.0477.00	AEROSOL SUSPENSION  Each inhalation contains: Beclomethasone Dipropionate 50 $\mu$ g.  Package with inhaler device for 200 doses.	Bronchial asthma.	Inhalation.  Adults:  Two to four inhalations, every 6 or 8 hours. Maximum dosage 20 inhalations/day.  Children from 6 to 12 years:  One to two inhalations, every 6 or 8 hours. Maximum dosage 10 inhalations/day.
	AEROSOL SUSPENSION  Each inhalation contains: Beclomethasone Dipropionate 250 $\mu$ g.		

010.000.2508.00

Package with inhaler device for 200 doses.

## Generalities

It reduces bronchial inflammation, suppresses the immune response and influences the metabolism of proteins, fats and carbohydrates.

## Risk in Pregnancy

c

## Adverse effects

Oropharyngeal candidiasis and irritative symptoms.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Patients with hemostasis disorders, epistaxis and atrophic rhinitis.

## Interactions

None of clinical importance.

**BENZONATE**

Clue	Description	Indications	Route of administration and dosage
010.000.2433.00	PEARL OR CAPSULE  Each pearl or capsule contains: Benzonate 100 mg.  Container with 20 pearls or capsules.	irritating cough	Oral.  Adults: 200 mg every 8 hours.  Children over 12 years old: 100 mg every 8 hours.
010.000.2435.00	SUPPOSITORY  Each suppository contains: Benzonate 50 mg.  Container with 6 suppositories.		Rectal.  Adults and Children over 10 years old: 100 mg every 8 hours.  Children from 6 to 10 years old 50 mg every 8 hours

## Generalities

Suppression of the cough reflex by direct action on the bulbar cough center. At the indicated doses, it does not have inhibitory effects on the respiratory nerve centers.

## Risk in Pregnancy C

## Adverse effects

Hives, nausea, sedation, headache, dizziness and abdominal pain.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and local anesthetics of the procaine type. Children under 6 years old.

## Interactions

It can enhance the effects of central nervous system depressant medications.

**BROMHEXINE**

Clue	Description	Indications	Route of administration and dosage
010.000.2158.00	SOLUTION  Each 100 mL contains: Bromhexine hydrochloride 80 mg.  Container with 100 mL and dispenser.	Broncho Diseases pulmonary with adherent sputum and mucostasis.	Oral.  Children between 5 and 10 years:  4 mg every 8 hours.
010.000.2159.00	COMPRESSED  Each tablet contains: Bromhexine hydrochloride 8 mg.  Package with 20 tablets.		Oral.  Adults and kids older than 12 years old:  8 mg every 8 hours.

## Generalities

It fluidifies bronchial secretions by fragmenting the acidic mucopolysaccharide fibers.

**Risk in Pregnancy** X 1st Quarter.

**Adverse effects**

Nausea, vomiting, rash, bronchospasm, angioedema, anaphylaxis.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug, breastfeeding and peptic ulcer.

Precautions: Liver and kidney failure.

**Interactions**

Concomitant administration with antibiotics (amoxicillin, cefuroxime, erythromycin, doxycycline) increases their concentrations in lung tissue.

## DEXTROMETHORPHAN

Clue	Description	Indications	Route of administration and dosage
010.000.2161.00	<p>SYRUP</p> <p>Each 100 mL contains: Dextromethorphan hydrobromide 200 mg.</p> <p>Container with 120 mL and dispenser (10 mg/5 mL).</p>	Irritant cough.	<p>Oral.</p> <p>Adults and kids older than 12 years old: 30 to 45 mg every 6 or 8 hours.</p> <p>Children from 6 to 12 years: 10 to 20 mg every 6 or 8 hours.</p>
010.000.2431.00	<p>SYRUP</p> <p>Each 100 mL contains: Dextromethorphan hydrobromide 300 mg.</p> <p>Container with 60 mL and dispenser (15 mg/5 mL).</p>		

**Generalities**

It suppresses the cough reflex by direct action on the cough center of the medulla oblongata.

**Risk in Pregnancy** c

**Adverse effects**

Drowsiness, dizziness, nausea and dry mouth.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug. Diabetes mellitus, bronchial asthma, gastritis, peptic ulcer, emphysema, liver failure. Children under 6 years old.

**Interactions**

With MAO inhibitors, antidepressants and tranquilizers.

## SALBUTAMOL

Clue	Description	Indications	Route of administration and dosage
010.000.0429.00	<p>AEROSOL SUSPENSION</p> <p>Each inhaler contains: Salbutamol 20 mg. -- Salbutamol sulfate equivalent to 20 mg salbutamol</p> <p>Inhaler container with 200 doses of 100 µg.</p>	<p>Bronchial asthma.</p> <p>Bronchitis.</p> <p>Emphysema.</p>	<p>Inhalation.</p> <p>Adults: Two inhalations every 8 hours.</p> <p>Children: Over 10 years, one inhalation every 8 hours.</p>
	<p>SYRUP</p> <p>Each 5 mL contains: Salbutamol sulfate equivalent to 2 mg</p>		<p>Oral</p> <p>Adults: 10 mL every 6-8 hours.</p>

010.000.0431.00	of salbutamol. Container with 60 mL.		Children from 6 to 12 years: 5 mL every 8 hours.  From 2 to 6 years: 2.5 mL every 8 hours.
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#### Generalities

Beta two adrenergic receptor agonist. It produces relaxation of bronchial, vascular and intestinal smooth muscle.

#### Risk in Pregnancy

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#### Adverse effects

Nausea, tachycardia, tremors, nervousness, palpitations, insomnia, bad taste in the mouth, oropharyngeal dryness, difficulty urinating, increase or decrease in blood pressure. Rarely anorexia, paleness, chest pain.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and to sympathomimetic amines, cardiac arrhythmias, coronary insufficiency.

Precautions: Hyperthyroidism, diabetics or patients with ketoacidosis, elderly.

#### Interactions

With beta blockers they reduce its therapeutic effect. With adrenergics, adverse effects increase.

### THEOPHYLLINE

Clue	Description	Indications	Route of administration and dosage
010.000.5075.00	ELIXIR  Each 100 mL contains: Theophylline anhydrous 533 mg.  Container with 450 mL and dispenser.	Bronchial asthma.  Bronchospasm.	Oral.  Adults: Start: 6 mg/kg body weight, followed by 2 to 3 mg/kg body weight every 4 hours (2 doses).  Maintain 1 to 3 mg/kg of body weight each 8 to 12 hours.  Children from 6 months to 9 years: Start: 6 mg/kg body weight, followed by 4 mg/kg body weight every 4 hours (3 doses). Support: 4 mg/kg body weight every 6 hours.
010.000.0437.00	TABLET OR TABLET OR RELEASE CAPSULE PROLONGED  Each tablet, tablet or capsule contains:  Theophylline anhydrous 100 mg.  Package with 20 extended-release tablets or tablets or capsules.		Oral.  Adults:  100 mg every 24 hours.

#### Generalities

It inhibits phosphodiesterase, an enzyme that degrades cyclic adenosine monophosphate and therefore has a relaxing effect on bronchial smooth muscle, reduces pulmonary vascular resistance and facilitates the contractility of the diaphragm.

#### Risk in Pregnancy C

#### Adverse effects

Nausea, vomiting, anorexia, diarrhea, urticaria, palpitations, tachycardia, flushing and arterial hypotension, dizziness, headache, insomnia and convulsions.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and xanthines (caffeine), cardiac arrhythmias, active peptic ulcer, uncontrolled seizures and children under 12 years of age.

Precautions: Elderly, cor pulmonale, liver or kidney failure, hyperthyroidism, diabetes mellitus.

#### Interactions

Rifampin decreases its plasma concentration. Erythromycin, troleandomycin, cimetidine, propranolol, ciprofloxacin, fluvoxamine and oral contraceptives increase their plasma values.

**TERBUTALLINE**

Clue	Description	Indications	Route of administration and dosage
010.000.0433.00	TABLET  Each tablet contains: Terbutaline sulfate 5 mg.  Package with 20 tablets.	Bronchial Asthma. Bronchospasm.	Oral.  Adults: 5 mg every 8 hours.  Children over 12 years old: 2.5 to 5 mg every 8 hours.

## Generalities

Relaxes bronchial smooth muscle by binding to beta 2 adrenergic receptors.

## Risk in Pregnancy

b

## Adverse effects

Nervousness, tremors, headache and drowsiness, palpitations, tachycardia, vomiting and nausea.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Systemic arterial hypertension, hyperthyroidism, heart disease, diabetes mellitus.

## Interactions

With MAO inhibitors it can cause severe hypertensive crisis. Propranolol and other similar beta blockers inhibit the bronchodilator effect of the drug.

**ALFA-DORNASA**

Clue	Description	Indications	Route of administration and dosage
010.000.5330.00	SOLUTION FOR INHALATION  Each vial contains: Alpha-dornase 2.5 mg.  Container with 6 vials of 2.5 mL.	Complications mucoviscidosis lungs.      the	Inhalation.  Children:  2.5 mg/day.

## Generalities

It is recombinant human deoxyribonuclease type 1 (rhDNase), which by unfolding the DNA, allows the mucus to be easily expelled.

## Risk in Pregnancy

b

## Adverse effects

Pharyngitis, dysphonia, laryngitis, rash.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, pregnancy, lactation, children under 5 years of age.

## Interactions

Other medications should not be mixed in the nebulizer.

**BECLOMETHASONE/ FORMOTEROL**

Clue	Description	Indications	Route of administration and dosage
	AEROSOL FOR INHALATION ORAL  Each gram contains:  Beclomethasone dipropionate 1.724 mg Formoterol fumarate dihydrate 0.103 mg	Usual treatment of asthma.	Oral inhalation.  Adults: One or two inhalations twice a day.

010.000.6157.00 Container with inhaler device with 120 doses (100 µg of Beclomethasone and 6 µg of formoterol/dose).		
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#### Generalities

The medicine is a fixed mixture of beclomethasone dipropionate and formoterol. As with other combinations of corticosteroids and 2-antagonists, additive effects are observed in terms of reducing asthma exacerbations. Beclomethasone dipropionate administered by inhalation at the recommended doses has a glucocorticoid anti-inflammatory action in the lungs that results in a reduction in asthma symptoms and exacerbations, with fewer adverse effects than when corticosteroids are administered systemically. Formoterol is a selective 2-adrenergic antagonist that relaxes bronchial smooth muscle in patients with reversible airway obstruction. The bronchodilator effect begins rapidly (1-3 minutes after inhalation) and is maintained for up to 12 hours after inhalation of a single dose.

#### Risk in Pregnancy

d

#### Adverse effects

Oral fungal infections, oral candidiasis, dysphonia and throat irritation.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to drugs.

Precautions: Patients with short QT, arrhythmias, ischemic heart disease, liver or kidney failure, under 18 years of age and over 69 years of age.

#### Interactions

The use of beta-blockers (including eye drops) should be avoided in asthmatic patients, as the effect of formoterol will be reduced or suppressed. Caution when prescribing theophylline and other beta2-adrenergic drugs concomitantly with formoterol. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines, monoamine oxidase inhibitors, and tricyclic antidepressants may prolong the QTc interval and increase the risk of ventricular arrhythmias.

### BECLOMETHASONE/ FORMOTEROL/ GLYCOPYRRONIUM

Code	Description	Indications	Route of administration and dosage
010.000.6223.00	<p>AEROSOL</p> <p>Each dose of pressurized inhalation solution contains:</p> <p>Anhydrous Beclomethasone Dipropionate 100 µg.</p> <p>Formoterol fumarate dihydrate extrafine 6 µg.</p> <p>Glycopyrronium Bromide 12.5 µg</p> <p>Cardboard box with bottle and inhaler device with dose counter with 120 doses (100 µg/ 6 µg/12.5 µg)</p>	<p>Symptomatic treatment and reduction of exacerbations adult patients with chronic obstructive pulmonary disease (COPD) GOLD stage C and D and who are at risk of exacerbations.</p>	<p>Mouthpiece for inhalation</p> <p>Adults</p> <p>The recommended dose is two inhalations of beclomethasone/formoterol/glycopyrronium twice a day.</p> <p>The maximum dose is two inhalations of beclomethasone/formoterol/glycopyrronium twice a day.</p>

#### Generalities

Beclomethasone dipropionate administered by inhalation at the recommended dose has a glucocorticoid anti-inflammatory action in the lungs. Formoterol is a selective 2-adrenergic agonist that relaxes bronchial smooth muscle in patients with reversible airway obstruction. Glycopyrronium is a high-affinity, long-acting muscarinic receptor antagonist (anticholinergic) used in inhaled form as a bronchodilator treatment.

#### Risk in Pregnancy

b

#### Adverse effects

Common reactions: Pneumonia, pharyngitis, oral candidiasis, urinary tract infection, nasopharyngitis, headache, dysphonia. Uncommon reactions: Influenza, oral fungal infection, oropharyngeal candidiasis, esophageal candidiasis, fungal pharyngitis, sinusitis, rhinitis, gastroenteritis, vulvovaginal candidiasis, granulocytopenia, allergic dermatitis, hypokalemia, hyperglycemia, agitation, tremor, dizziness, dysgeusia, hypoesthesia, otosalginitis, fibrillation atrial, interval prolongation, electrocardiographic QTc, tachycardia, tachyarrhythmia, palpitations, hyperemia, flushing,

hypertension, asthma attack, cough, productive cough, throat irritation, epistaxis, pharyngeal erythema, diarrhea, dry mouth, dysphagia, nausea, dyspepsia, burning sensation on the lips, dental caries, stomatitis, skin rash, urticaria, pruritus, hyperhidrosis, muscle spasms, myalgia, pain in extremities, chest pain, musculoskeletal, fatigue, increased C-reactive protein, increased platelet count, increased free fatty acids, increased blood insulin, increased blood ketone bodies, decrease in cortisol in the blood. Rare reactions: Lower respiratory tract (fungal) infection, hypersensitivity reactions including erythema, edema of lips, face, eyes and pharynx, decreased appetite, insomnia, hypersomnia, angina pectoris, extrasystoles, nodal rhythm, sinus bradycardia and blood extravasation, paradoxical bronchospasms, asthmatic exacerbations, oropharyngeal pain, pharyngeal inflammation, dry throat, angioedema, dysuria, urinary retention, nephritis, asthenia, increased blood pressure and decreased blood pressure. Very rare reactions: Suppression of adrenal function, glaucoma, cataracts, dyspnea, growth retardation, peripheral edema, decreased bone density. Reactions with frequency not known: Blurred vision.

#### Contraindications and Precautions

Contraindication: Hypersensitivity to the active ingredients and/or any of the excipients. Precautions: Not suitable for the treatment of exacerbations, hypersensitivity, paradoxical bronchospasm, deterioration of the disease, cardiovascular effects, pneumonia in patients with COPD, systemic corticosteroid defects (like all inhaled drugs containing corticosteroids should be administered with caution in patients with active or inactive pulmonary tuberculosis, fungal and viral infections in the respiratory tract), hypokalemia, hyperglycemia, anticholinergic effect, patients with severe renal failure, patients with severe liver failure, prevention of oropharyngeal infections, visual disturbances, treatment reduction.

#### Interactions

Glycopyrronium is mainly eliminated through the kidneys, drug interactions could occur with medications that affect renal excretion mechanisms. Beclomethasone is less dependent on CYP3A metabolism, so interactions are unlikely; the production of systemic reactions with the concomitant use of strong CYP3A inhibitors (ritonavir, cobicistat) is not ruled out. Formoterol: Avoid non-selective beta-blockers (including eye drops), if administered, the effect of formoterol will be reduced or suppressed. Caution is required when prescribing other beta-adrenergic medications concomitantly with formoterol. Concomitant treatment with quinidine, disopyramide, procainamide, antihistamines, monoamine oxidase inhibitors, tricyclic antidepressants, and phenothiazines may prolong the QT interval and increase the risk of ventricular arrhythmias. L-dopa, L-thyroxine, oxytocin and alcohol can reduce cardiac tolerance towards sympathomimetics. Concomitant treatment with monoamine oxidase inhibitors, including drugs with similar properties with furazolidone and procarbazine can precipitate hypertensive reactions. There is an increased risk of arrhythmias in patients receiving concomitant anesthesia with halogenated hydrocarbons. Concomitant treatment with xanthines, steroids or diuretics may enhance the hypokalemic effect of 2-agonist. Hypokalemia may increase predisposition or arrhythmias in patients treated with cardiac glycosides.

### ***BENRALIZUMAB (In Catalog II program)***

Clue	Description	Indications	Route of administration and dosage
010.000.6310.00	<p>INJECTABLE SOLUTION</p> <p>Each prefilled syringe contains: Benralizumab 30 mg</p> <p>Cardboard box with a single-dose prefilled syringe (30 mg/mL)</p>	Complement of Maintenance treatment for severe asthma with uncontrolled eosinophilic phenotype in adult patients.	<p>Subcutaneous</p> <p>Adults: 30 mg by subcutaneous injection every 4 weeks for the first 3 doses and every 8 thereafter weeks.</p>

#### Generalities

Benralizumab is a humanized, anti-eosinophilic, non-fucosylated monoclonal antibody (IgG1, kappa).

#### Risk in Pregnancy

#### Adverse effects

Headache, pharyngitis, fever, injection site reactions, hypersensitivity reactions.

#### Contraindications and Precautions

Contraindications: Known hypersensitivity to benralizumab or any of its excipients; in anaphylaxis with other monoclonal antibodies of the IgG type; in pregnancy and lactation; and in those under 18 years of age

#### Interactions

Cytochrome P450 enzymes, efflux pumps and protein binding mechanisms are not involved in the clearance of Benralizumab. There is no evidence of IL-5R $\alpha$  expression in hepatocytes. The reduction of eosinophils produced systemic proinflammatory cytokines.

No

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**BERACTANT**

Clue	Description	Indications	Route of administration and dosage
010.000.5331.00	INJECTABLE SUSPENSION  Each mL contains: Beractant (lung phospholipids of bovine origin) 25 mg.  Package with 8 mL vial with or without endotracheal cannula.	Prevention and treatment of respiratory distress syndrome.	intratracheal.  Premature:  100 mg/kg body weight, repeat the dose according to therapeutic response after 6 hours.

## Generalities

Lung extract that contains phospholipids, neutral lipids, fatty acids and surfactant proteins that reduces alveolar surface tension and prevents collapse at resting transpulmonary pressures.

## Risk in Pregnancy

c

## Adverse effects

Transient bradycardia, reflux and obstruction in the endotracheal tube, paleness, arterial hypotension, hypocapnia and hypercapnia and apnea.

## Contraindications and Precautions

Contraindications. Hypersensitivity to the drug, risk of post-treatment sepsis.  
 Precautions: Monitor the patency of the endotracheal cannula.

## Interactions

None of clinical importance.

**BOSENTAN**

Clue	Description	Indications	Route of administration and dosage
010.000.5600.00	TABLET  Each tablet contains: Bosentan 62.5 mg.  Package with 60 tablets.	Pulmonary arterial hypertension.	Oral.  Adults and kids older than 12 years old:  Initial dose: 62.5 mg every 12 hours for 4 weeks.
010.000.5601.00	TABLET  Each tablet contains: Bosentan 125 mg.  Package with 60 tablets.		Maintenance dose: 125 mg every 12 hours for at least 4 weeks.
010.000.6139.00	TABLET  Each tablet contains: Bosentan monohydrate equivalent to 32 mg of bosentan.  Package with 56 tablets.		Oral.  Children over 3 years old 2 mg/kg of body weight, every 12 hours.

## Generalities

Bosentan is a selective antagonist of endothelin A and B receptors, indicated in patients with pulmonary arterial hypertension, decreasing vascular resistance to improve exercise capacity and cardiorespiratory symptoms, delaying clinical deterioration.

## Risk in Pregnancy

c

## Adverse effects

Upper respiratory tract infection, nasopharyngitis, pneumonia, lower extremity edema, dyspepsia, dry mouth, headache, facial flushing, hypotension, pruritus, fatigue, abnormal liver function.

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.  
 Precautions: In moderate to severe liver failure, Child-Pugh Class B or C. Baseline values of hepatic aminotransferases, that is, aspartate aminotransferase and/or alanine aminotransferase, greater than 3 times the

upper limit of normal. Concomitant use of cyclosporine A.

#### Interactions

Ciclosporin A increases the plasma concentrations of bosentan, its use together with glibenclamide decreases its hypoglycemic effect, contraceptives decrease its bioavailability, and simvastatin decreases the plasma concentrations of bosentan.

### IPRATROPIUM BROMIDE/FENOTEROL

Clue	Description	Indications	Route of administration and dosage
010.000.6330.00	<p>AEROSOL</p> <p>Each mL contains: Ipratropium bromide equivalent to: 0.394 mg. Fenoterol equivalent to: 0.938 mg</p> <p>Package with a pressurized bottle with inhalation device 10 mL = 200 doses.</p>	<p>Bronchodilator for prevent and treat the symptoms of diseases that cause chronic airway obstruction with bronchospasm</p> <p>reversible.</p>	<p>Oral inhalation</p> <p>Adults and children over 6 years of age: Administer two shots.</p> <p>In more severe cases, if breathing has not improved noticeably after 5 minutes, two more shots may be given.</p>

#### Generalities

A bronchodilator that produces a topical effect on the airway, ipratropium bromide acts on muscarinic receptors, while salbutamol acts on  $\beta_2$  (beta) adrenergic receptors in the airway.

#### Risk in Pregnancy

c

#### Adverse effects

It can cause nervousness, xerostomia, headache, dizziness and fine skeletal muscle tremor. Tachycardia and palpitations. Alterations in gastrointestinal motility (vomiting, constipation and diarrhea) and urinary retention that have been reported to be reversible.

#### Contraindications and Precautions

Contraindication: patients with known hypersensitivity to fenoterol or atropine-like substances or any other component of the formula. Likewise, in patients with obstructive hypertrophic cardiomyopathy and tachyarrhythmia.

#### Interactions

Other  $\beta$ -(beta) adrenergics, anticholinergics and xanthine derivatives can increase the bronchodilator effect, and may also increase adverse reactions.

The concurrent administration of  $\beta$ -(beta) blockers, a potentially severe reduction in bronchodilation may occur.

Susceptibility to the cardiovascular effects of  $\beta$ -agonists may be increased during inhalation of halogenated hydrocarbon anesthetics such as halothane, trichlorethylene and enflurane.

### BUDESONIDE

Clue	Description	Indications	Route of administration and dosage
010.000.4332.00	<p>SUSPENSION FOR NEBULIZE</p> <p>Each container contains: Budesonide (micronized) 0.250 mg.</p> <p>Container with 5 containers with 2 mL.</p>	<p>Bronchial asthma.</p> <p>CRUP (Acute viral upper respiratory tract infection also known as viral laryngotracheobronchitis or subglottic laryngitis) in infants and children.</p>	<p>Inhalation.</p> <p>Adults: 400-2400 <math>\mu\text{g/day}</math>, divided every 6 or 8 hours.</p> <p>Maintenance dose 200-400 <math>\mu\text{g/day}</math>. Maximum dose 1,600 <math>\mu\text{g/day}</math>.</p> <p>Children: 200 to 400 <math>\mu\text{g/day}</math>, divided every 6 or 8 hours.</p>
010.000.4332.01	<p>Container with 20 containers with 2 mL.</p>		
010.000.4333.00	<p>SUSPENSION FOR NEBULIZE</p> <p>Each container contains: Budesonide (micronized) 0.500 mg.</p> <p>Container with 5 containers with 2 mL.</p>		<p>Maximum dose 800 <math>\mu\text{g/day}</math>.</p>

010.000.4333.01	Container with 20 containers with 2 mL.		
010.000.4334.00	DUST  Each dose contains: Budesonide (micronized) 100 µg.  Container with 200 doses and inhaler device.		
010.000.6150.00	AEROSOL FOR ORAL INHALATION  Each gram contains: Budesonide 4,285 mg  Pressurized container with 200 doses of 200 µg each and inhaler device.	Mucolytic. Steroid anti-inflammatory	Mouthpiece for inhalation  Adults: Initially the treatment should be: 200-400 µg (1 to 2 inhalations) 2 times a day, in the morning and afternoon. During periods of severe asthma the daily dose can be increased to 1600 µg, which is equivalent to 1 or 2 inhalations up to 4 times a day. The maximum dose for patients previously treated with bronchodilators is 800 µg per day. If necessary, they can be used in severe asthma up to 4 doses 2 times a day.  Once the desired clinical effects are obtained, the maintenance dose should be gradually reduced to the minimum amount necessary to control symptoms.  Children from 6 to 12 years: At the beginning of treatment the dose should be 200 µg (1 inhalation) 2 times a day. During periods of severe asthma, the dose can be increased to 400 µg twice a day, reducing the dose once symptoms disappear, until the lowest effective maintenance dose is achieved.

#### Generalities

Budesonide is a racemic mixture of 22R (R) and 22S (S) epimers. No interconversion has been observed in vivo between the epimers. Budesonide has a high relative affinity for the glucocorticoid receptor and the R epimer has an affinity twice as high as the S epimer. It is a moderately lipophilic compound that shows rapid reuptake in the airway mucosa. Although topical budesonide is rapidly and widely absorbed by the lungs, there are no signs of intrapulmonary drug metabolism except in combination with fatty acids. In vitro assays did not show any oxidative or reductive metabolism of budesonide by human lung homogenates.

#### Risk in Pregnancy

d

#### Adverse effects

Throat irritation, cough and hoarseness; oropharyngeal dryness and bad taste in the mouth. Superinfection by *Candida spp.* in the oropharyngeal cavity, esophageal candidiasis. Allergic skin reactions such as urticaria, rash and dermatitis, associated with the use of topical corticosteroids. Nervousness, restlessness, depression and pulmonary infiltrates with eosinophilia.

#### Contraindications and Precautions

Contraindications: hypersensitivity to the drug. Budesonide is contraindicated in patients with active or latent tuberculosis, herpes simplex, ocular, untreated systemic fungal, bacterial or viral infections. Evolving digestive ulcer, pulmonary fungal infection. It should not be administered to patients with moderate to severe bronchiectasis.

#### Interactions

Budesonide is metabolized by cytochrome P450 3a, so drugs known to inhibit CYP3A such as ketoconazole and cyclosporine could at least potentially reduce budesonide clearance. Due to the low doses of budesonide administered by inhalation, the ability of budesonide to decrease other competitive elimination is negligible.

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**BUDESONIDE-FORMOTEROL**

Clue	Description	Indications	Route of administration and dosage
010.000.0445.00	DUST  Each gram contains: Budesonide 90 mg. Formoterol fumarate dihydrate 5 mg.  Container with metered inhaler bottle with 60 doses with 80yg /4.5 yg each.	Bronchial asthma. Chronic obstructive pulmonary disease.	Inhalation.  Adolescents and adults (over 12 years old). 80/4.5 yg and 160/4.5 yg of 1-2 inhalations, every 12 to 24 hours.  Maximum daily maintenance dose 320 yg/18 yg.
010.000.0446.00	DUST  Each gram contains: Budesonide 180 mg. Formoterol fumarate dihydrate 5 mg.  Container with metered inhaler bottle with 60 doses with 160yg /4.5yg each.		In case of worsening asthma, the dose may be temporarily increased to a maximum of four inhalations each. 12 hours.  Children (over 4 years old) 80 yg /4.5 yg.  1-2 inhalations, every 12 hours. The maximum daily maintenance dose is  160/ 9 yg.

## Generalities

Steroid anti-inflammatory and bronchodilator.

## Risk in Pregnancy C

## Adverse effects

Tremor, palpitations, headache, candida infections, pharyngeal irritation, cough, dysphonia, tachycardia, nausea, agitation, sleep disturbances, bronchospasm, rash, urticaria, pruritus, ecchymosis.

## Contraindications and Precautions

Contraindications: Hypersensitivity to drugs or inhaled lactose, thyrotoxicosis, ischemic heart disease, tachyarrhythmias, hyperthyroidism, tricyclic antidepressants, simultaneous use with MAO inhibitors, pregnancy and lactation, children under 4 years of age.

## Interactions

Ketoconazole may increase plasma concentrations.

**CAFFEINE CITRATE**

Clue	Description	Indications	Route of administration and dosage
010.000.6083.00	INJECTABLE SOLUTION ORAL SOLUTION  Each milliliter contains: Caffeine citrate 20 mg. equivalent to 10 mg. of caffeine  Package with 10 vials with 3 mL (30 mg caffeine/ 3 mL).	Treatment of apnea of premature in the short term, in premature newborns 37 weeks of gestational < age.	Intravenous.  Premature newborn children < 37 weeks gestational age.  Loading dose: 1 mL/Kg of body weight, for 30 minutes, using a syringe infusion pump.
010.000.6083.01	Package with 10 vials with 1 mL (10 mg caffeine/ 1 mL).		Maintenance dose (24 hours after loading dose):  Intravenous: 0.25 mL/kg body weight, for 10 minutes, every 24 hours, using a syringe infusion pump.  or Oral (enteral or with the use of a nasogastric tube):  0.25 mL/Kg of body weight, for 10 minutes, every 24 hours.

## Generalities

It is a mild bronchial smooth muscle relaxant, CNS stimulant, cardiac muscle stimulant and diuretic.

Risk in Pregnancy C

Adverse effects

Necrotizing enterocolitis and tachycardia

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Baseline serum caffeine levels should be measured in infants born to mothers who consume caffeine before birth, as caffeine easily crosses the placenta. It should be used with caution in infants with seizure disorders, cardiovascular disease, kidney or liver failure.

Interactions

Few data exist on drug interactions with caffeine in preterm infants.

## FLUTICASONE

Clue	Description	Indications	Route of administration and dosage
010.000.0440.00	AEROSOL SUSPENSION  Each dose contains: Fluticasone propionate 50µg.  Package with a pressurized bottle for 60 doses.	Bronchial asthma.	Inhalation.  Adults:  100 to 1000 µg every 12 hours, according to the severity of the condition.
010.000.0450.00	AEROSOL SUSPENSION  Each dose contains: Fluticasone propionate 50µg.  Package with a pressurized bottle for 120 doses.		Children over 4 years: 50 to 100 µg every 12 hours.

Generalities

Bronchial anti-inflammatory, anti-allergic and antiproliferative glucocorticoid.

Risk in Pregnancy

C

Adverse effects

Risk of paradoxical bronchospasm.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Interactions

None of clinical importance.

## FLUTICASONE, VILANTEROL

Clue	Description	Indications	Route of administration and dosage
010.000.5980.00	POWDER FOR INHALATION  Each dose contains: Fluticasone furoate 100 µg. Vilanterol trifenate equivalent to 25 µg. of vilanterol.  Inhaler device container with 30 doses.	Treatment of Chronic Obstructive Pulmonary Disease (COPD).  Bronchial asthma.	Oral inhalation.  Adults and children over 12 years of age.  One inhalation once a day.

Generalities

Fluticasone furoate and vilanterol are a synthetic corticosteroid and a long-acting selective  $\beta_2$  receptor agonist. The interaction of both activates the  $\beta_2$  receptor gene, increasing the number of receptors and sensitivity, and LABAs prepare the glucocorticoid receptor for steroid-dependent activation and increase cellular nuclear translocation. These synergistic interactions are reflected in an increase in inflammatory activity.

anti-

Risk in Pregnancy C

## Adverse effects

Headache, nasopharyngitis, upper respiratory tract infection and oral candidiasis.

## Contraindications and Precautions

Contraindications: Hypersensitivity to drugs or patients with severe allergy to milk protein.

Precautions: It should not be used to treat symptoms of acute asthma or an acute exacerbation of COPD, for which a rapid-acting bronchodilator is required. Increased use of rapid-acting bronchodilators to relieve symptoms indicates deterioration in asthma control, so the patient should be seen by a doctor.

Patients should not discontinue treatment with Fluticasone, Vilanterol, for asthma or COPD without physician supervision, as symptoms may recur after discontinuation.

As with other inhaled treatments, paradoxical bronchospasm may occur, with an immediate increase in wheezing after dosing. Fluticasone, Vilanterol should be discontinued immediately, the patient should be evaluated and alternative treatment should be initiated if necessary.

Cardiovascular effects, such as cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles, may be seen with sympathomimetic drugs, including Fluticasone, Vilanterol. Therefore Fluticasone, Vilanterol should be used with caution in patients with severe cardiovascular disease.

## Interactions

Concurrent use with beta blockers should be avoided.

**PORK LUNG PHOSPHOLIPIDS**

Clue	Description	Indications	Route of administration and dosage
	SUSPENSION	Membrane syndrome hyaline.	Endotracheal.
	Each milliliter contains: Porcine lung phospholipids 80 mg.		Newborn children:
010.000.5335.00	Container with 1.5 mL.		Treatment. Single dose: 100 or 200 mg/kg body weight bodily. Additional dose: two doses of 100 mg/kg body weight, the first should be administered immediately and the second after about 12 hours.
010.000.5335.01	Container with 3 mL.		Prophylactic. Initial dose: 100 or 200 mg/kg body weight within the first 15 minutes of birth. An additional dose of 100 mg/kg body weight may be given,  6 to 12 hours after the first dose, and another dose 12 hours later.

## Generalities

Natural surfactant prepared from pig lung, containing polar lipids, in particular pig lung phospholipids and specific low molecular weight hydrophobic proteins SP-b and SP-C. Its effect is to reduce the surface tension of the air-liquid interfaces, stabilizing the alveoli, thus preventing their collapse.

## Risk in Pregnancy

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## Adverse effects

No adverse reactions have been described.

## Contraindications and Precautions

Hypersensitivity to the drug or the components of the formula.

## Interactions

They are not known until now.

**ILOPROST**

Clue	Description	Indications	Route of administration and dosage
	NEBULIZING SOLUTION	Treatment of Hypertension	Nebulization.
	Each milliliter contains:	Arterial Primary pulmonary in	Adults.

010.000.5848.00	Iloprost tromethanol 0.0134 mg equivalent to 0.010 mg. from Iloprost.  Container with 30 vials with 2 mL each.	adult patients with functional class III and IV.	Each inhalation session begins with 2.5 µg. It can be increased to 5.0 µg depending on the patient's needs and tolerance.  The dose is administered 6 to 9 times a day, depending on needs and tolerance.  Each inhalation session lasts 4 to 10 minutes.
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#### Generalities

Iloprost is a stable, synthetic analogue of prostacyclin, which has a high affinity for the prostacyclin (PI) receptor. It is through the second messenger signaling pathway cAMP (cyclic adenosine monophosphate) that produces the following effects: Vasodilation of arteries and venules, inhibition of platelet activation, adhesion and aggregation. After inhalation, it produces direct vasodilation of the pulmonary arterial bed with a reduction in pulmonary arterial pressure levels, as well as levels of pulmonary vascular resistance, with increases in cardiac output, as well as mixed venous saturation. The effects on peripheral vascular resistance and systemic blood pressure are minimal. The elimination of iloprost is reduced in patients with hepatic impairment and in those with renal failure requiring dialysis. An initial dose adjustment is recommended, with dosing intervals of at least 3 hours.

#### Risk in Pregnancy D

#### Adverse effects

Headache, symptoms caused by vasodilation, cough, nausea, jaw pain, lockjaw, syncope. Bleeding disorders (hematomas) have also been observed; it should be noted that a high proportion of patients with PAH are treated with anticoagulants. However, the frequency of bleeding episodes did not differ between patients treated with iloprost and those receiving placebo.

#### Contraindications and Precautions

Contraindications: Pregnancy, lactation, disorders in which the effects of iloprost on platelets may increase the risk of bleeding (active peptic ulcer, trauma, intracranial hemorrhage), severe coronary artery disease or unstable angina, myocardial infarction in the previous six months, decompensated heart failure without strict medical supervision, severe arrhythmias, suspected acute pulmonary edema; cerebral vascular events in the previous 3 months, pulmonary arterial hypertension due to veno-occlusive disease, congenital or acquired valvular heart disease with clinically significant alterations in myocardial function unrelated to pulmonary arterial hypertension, hypersensitivity to iloprost or any of the excipients. Pulmonary hypertension due to thromboembolism if surgical treatment is feasible.

Precautions: patients with systolic blood pressure less than 85 mm Hg, bronchial hyperreactivity.

#### Interactions

Iloprost may increase the antihypertensive action of beta-blockers, calcium antagonists, ACE inhibitors and other antihypertensive or vasodilator agents. Its use with anticoagulants (heparin, coumarin anticoagulants) or with other inhibitors of platelet aggregation (acetylsalicylic acid, non-steroidal anti-inflammatory drugs, phosphodiesterase inhibitors and nitro vasodilators) may increase the risk of bleeding.

## INDACATEROL / GLYCOPYRRONIUM

Clue	Description	Indications	Route of administration and dosage
010.000.6021.00	CAPSULE  Each capsule contains: Indacaterol maleate equivalent to 110 µg indacaterol Glycopyrronium Bromide equivalent to 50 µg of Glycopyrronium  Package with 30 capsules with powder for inhalation (not ingestible), and an inhalation device.	Treatment maintenance bronchodilator to control symptoms of moderate to severe Chronic Obstructive Pulmonary Disease (COPD) with risk of exacerbations.	Oral inhalation.  Adults: One capsule daily.

#### Generalities

Indacaterol/Glycopyrronium is an  $\beta_2$  adrenergic agonist and muscarinic receptor antagonist (anticholinergic). When Indacaterol and Glycopyrronium are administered together, their effectiveness is additive, since they act differently on different receptors and pathways to achieve smooth muscle relaxation. Due to the differential density of  $\beta_2$  adrenergic receptors and M3 receptors between the central airways and the more peripheral airways,  $\beta_2$  agonists should relax the latter more effectively, while an anticholinergic compound could

be more effective in larger airways.

Risk in Pregnancy

b

Adverse effects

Stuffy nose, sneezing, cough, headache with or without fever, combination of sore throat and runny nose (rhinopharyngitis), painful urination and frequent urination, feeling of pressure or pain in the cheeks and forehead, runny or stuffy nose, dizziness, headache, cough, sore throat, upset stomach, indigestion, cavities, pain in muscles, ligaments, tendons, joints and bones, fever, chest pain.

Changes in vision, increased pressure in the eye, temporary blurring of vision, visual halos or colored images in association with red eyes. Pressing chest pain with increased sweating (signs of insufficient blood and oxygen supply to the heart, this may be a serious heart problem such as ischemic heart disease). Excessive thirst, large volume of urine, increased appetite with weight loss, tiredness You may experience symptoms of an allergic reaction, such as difficulty breathing or swallowing, swelling of the tongue, lips and face, skin rash, itching and hives. Irregular heartbeat.

Contraindications and Precautions

Contraindications: Hypersensitivity to drugs.

Precautions: Indacaterol/Glycopyrronium in combination should not be used for the treatment of asthma, as there are no data in this indication. Indacaterol/Glycopyrronium is not indicated in the treatment of acute episodes of bronchospasm.

Interactions

The simultaneous use of  $\beta_2$  adrenergic blockers is not recommended since they can reduce or antagonize the effects of  $\beta_2$  adrenergic agonists as well as medications that prolong the QT interval (monoamine oxidase inhibitors, tricyclic antidepressants), anticholinergics since the administration has not been studied. simultaneous with the Indacaterol/Glycopyrronium combination.

## IPRATROPIUM

Code	Description	Indications	Route of administration and dosage
010.000.2162.00	AEROSOL SUSPENSION Each g contains: Ipratropium bromide 0.286 mg (20 $\mu$ g per nebulization).  Container with 15 mL (21.0 g) as an aerosol.	Bronchospasm in cases of bronchial asthma.  Bronchospasm in chronic obstructive pulmonary disease.	Inhalation.  Adults:  Acute attack: 2-3 inhalations, which can be repeated 2 hours later. Maintenance: 2 inhalations every 4-6 hours.
010.000.2162.01	AEROSOL SUSPENSION Each g contains: Ipratropium bromide 0.374 mg (20 $\mu$ g per nebulization).  Container with 10 mL (11.22 g) as an aerosol.		
010.000.2187.00	SOLUTION Each 100 mL contains: Ipratropium bromide monohydrate equivalent to 25 mg. of ipratropium bromide.  Container with vial bottle with 20 mL.		Inhalation.  Adults and people over 12 years of age (diluted with physiological solution up to 3-4 mL):  Acute attack: 2 mL (40 drops = 0.5 mg), Repeat according to therapeutic response.  Maintenance: 2 mL (40 drops = 0.5 mg) every 6-8 hours.

Generalities

Anticholinergic that acts by inhibiting vagal reflexes by antagonizing the acetylcholine receptor.

Risk in Pregnancy

b

Adverse effects

Headache, nausea and dryness of the oral mucosa.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and atropine. Glaucoma, prostatic hypertrophy. Pregnancy, breastfeeding and children under 12 years of age

Precautions: Obstruction of the bladder neck.

Interactions



With antimuscarinics, adverse effects increase.

## IPRATROPIUM-SALBUTAMOL

Clue	Description	Indications	Route of administration and dosage
010.000.2188.00	<p>SOLUTION</p> <p>Each vial contains: Ipratropium bromide monohydrate equivalent to 0.500 mg. of ipratropium bromide.</p> <p>Salbutamol sulfate equivalent to 2.500 mg. of salbutamol.</p> <p>Container with 10 vials of 2.5 mL.</p>	<p>Asthma bronchospasm in cases</p> <p>bronchial</p> <p>Bronchospasm in chronic obstructive pulmonary disease</p>	<p>Inhalation.</p> <p>Children 2-12 years:</p> <p>Sharp attack: 30 <math>\mu</math>g-150 <math>\mu</math>g (3 drops)/kg body weight every 6-8 hours.</p> <p>Maintenance: 30 <math>\mu</math>g-150 <math>\mu</math>g (3 drops)/kg body weight every 6-8 hours.</p> <p>Adults and kids older than 12 years old:</p> <p>Sharp attack: 0,500 mg-2,500 mg. Repeat according to therapeutic response.</p> <p>Maintenance: 0,500 mg-2,500 mg every 6-8 hours.</p>
010.000.2190.00	<p>AEROSOL SUSPENSION</p> <p>Each g contains: Ipratropium bromide monohydrate equivalent to 0.286 mg of ipratropium. Salbutamol sulfate equivalent to 1,423 mg of salbutamol.</p> <p>Container with a pressurized bottle with 14g without spacer.</p>		<p>Inhalation</p> <p>Children 2-12 years: 1-2 inhalations every 6-8 hours.</p> <p>Adults and people over 12 years old. 2 inhalations every 6 hours.</p> <p>It can be increased to a maximum of 12 inhalations/day, according to therapeutic response.</p>
010.000.2190.01	<p>SOLUTION FOR INHALATION</p> <p>Each shot provides: Ipratropium bromide monohydrate equivalent to 20 <math>\mu</math>g of ipratropium bromide.</p> <p>Salbutamol sulfate equivalent to 100 <math>\mu</math>g of salbutamol.</p> <p>Container with 120 shots (120 doses).</p>		<p>Inhalation.</p> <p>Children from 2 to 12 years: 1 inhalation every 8 hours.</p> <p>Adults and people over 12 years of age: 1 to 2 inhalations every 8 hours.</p> <p>It can be increased to a maximum of 6 inhalations every 24 hours, according to therapeutic response.</p>

### Generalities

Locally acting bronchodilators, ipratropium bromide acts on muscarinic receptors, while salbutamol on lung  $\beta_2$  adrenergic receptors.

### Risk in Pregnancy C

### Adverse effects

Slight tremor of extremities, nervousness, tachycardia, dizziness, palpitations or headache.

### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and atropinics, hypertrophic obstructive cardiomyopathy, tachyarrhythmias, arterial hypertension, thyrotoxicosis, hyperthyroidism, Parkinson's disease.

### Interactions

Simultaneous administration of  $\beta$  blockers decreases their effectiveness. Halothane or enflurane may increase the potential arrhythmogenic salbutamol.

## MACITENTÁN (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
	TABLET	Second Oral Treatment.	

010.000.6022.00	Each tablet contains: Macitentan 10 mg  Package with 28 tablets.	line for Pulmonary Arterial Hypertension, in combination with phosphodiesterase 5 inhibitors.	Adults: 10 mg every 24 hours.
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#### Generalities

Endothelin (ET)-1 and its receptors (ETA and ETB) mediate different effects such as vasoconstriction, fibrosis, proliferation, hypertrophy and inflammation. In disease conditions such as PAH, the local ET system is increased and mediates vascular hypertrophy and organ damage.

#### Risk in Pregnancy

c

#### Adverse effects

Nasopharyngitis, bronchitis, pharyngitis, flu, urinary infection, anemia, headache, hypotension, nasal congestion, edema, fluid retention.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Treatment with Macitentan should not be initiated in patients with severe hepatic impairment or elevated aminotransferase levels ( $> 3 \times$  ULN), and is not recommended in patients with moderate hepatic impairment.

A determination of liver enzyme levels should be performed before starting treatment with Macitentan.

The initiation of Macitentan is not recommended in patients with severe anemia. It is recommended to measure the concentrations of hemoglobin before the start of treatment and repeat measurements during treatment as clinically indicated.

Cases of pulmonary edema have been reported with vasodilators (mainly prostacyclins) when used in patients with pulmonary veno-occlusive disease. Consequently, if signs of pulmonary edema occur with administration of macitentan in patients with PAH, the possibility of an underlying disease should be considered. pulmonary veno-occlusive.

Patients with renal impairment may be at increased risk of hypotension and anemia during treatment with macitentan.

#### Interactions

A reduced efficacy of macitentan may occur in the presence of strong CYP3A4 inducers. The combination of macitentan with strong CYP3A4 inducers (e.g., rifampin, St. John's wort, carbamazepine, and phenytoin) should be avoided.

In the presence of ketoconazole 400 mg once daily, a strong CYP3A4 inhibitor, macitentan exposure was increased approximately 2-fold. The predicted increase was approximately 3-fold in the presence of ketoconazole 200 mg twice daily with a physiology-based pharmacokinetic (PKBF) model.

Concomitant treatment with rifampicin 600 mg daily, a strong CYP3A4 inducer, reduced steady-state exposure to macitentan by 79%, but did not affect exposure to the active metabolite. Reduced efficacy of macitentan should be considered in the presence of a strong CYP3A4 inducer such as rifampicin. The combination of macitentan with strong CYP3A4 inducers should be avoided.

### MEPOLIZUMAB (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
010.000.6311.00	Injectable solution:  Each vial with lyophilized powder contains:  Mepolizumab 100 mg  Container with vial with 144 mg of lyophilized powder to reconstitute with 1.2 mL of sterile water, to allow an extractable volume of 100 mg/mL.	Refractory severe eosinophilic asthma: indicated as  a complementary maintenance treatment for adult and adolescent patients over  12 years old.	Subcutaneous application injection  Adults and adolescents over 12 years of age:  The recommended dose is 100 mg each 4 weeks, applied subcutaneously.
010.000.6311.01 Pre-filled pen	The pre-filled pen contains:  Mepolizumab 100mg  Cardboard box with 1 pre-filled pen with 1 mL (100mg/mL)  All presentations with attached instructions.		

#### Generalities

Mepolizumab is a humanized monoclonal antibody (IgG1, kappa), directed at interleukin-5 (IL-5), the main

cytokine responsible for the growth, activation and survival of eosinophils. Mepolizumab inhibits IL-5 signaling and thereby decreases the production and survival of eosinophils.

Risk in Pregnancy B1

Adverse effects

Pharyngitis, lower respiratory tract infection, urinary tract infection, nasal congestion, upper abdominal pain, eczema, back pain, pyrexia and headache.

Contraindications and Precautions

Contraindications: Hypersensitivity to mepolizumab or any of the excipients of the formula, during pregnancy and lactation, or in children under 12 years of age.

Precautions: hypersensitivity reactions (eg anaphylaxis, angioedema, bronchospasm, arterial hypotension, urticaria, rash); The use of mepolizumab is not recommended to treat acute bronchospasm or status asthmaticus; Infections such as herpes zoster have been described in patients receiving mepolizumab. Abrupt discontinuation of inhaled or systemic corticosteroids at the beginning of mepolizumab treatment is not recommended; gradual tapering is recommended, if appropriate.

Interactions

No formal trial or studies have been designed or performed to evaluate interactions with mepolizumab administration.

## MONTELUKAST

Clue	Description	Indications	Route of administration and dosage
010.000.4329.00	<p>CHEWABLE TABLET</p> <p>Each tablet contains: Montelukast sodium equivalent to 5 mg montelukast.</p> <p>Package with 30 tablets.</p>	<p>Bronchial asthma.</p> <p>Allergic rhinitis.</p>	<p>Oral.</p> <p>Children from 6 to 14 years:</p> <p>5 mg every 24 hours.</p>
010.000.4330.00	<p>COATED TABLET</p> <p>Each tablet contains: Montelukast sodium equivalent to 10 mg montelukast.</p> <p>Package with 30 tablets.</p>		<p>Oral.</p> <p>Adults:</p> <p>10 mg every 24 hours.</p>
<p>010.000.4335.00</p> <p>010.000.4335.01</p> <p>010.000.4335.02</p>	<p>GRANULATED</p> <p>Each envelope contains: Montelukast sodium equivalent 4 mg. from montelukast.</p> <p>Container with 10 sachets.</p> <p>Container with 20 sachets.</p> <p>Container with 30 sachets.</p>		<p>Oral.</p> <p>Children over 2 years:</p> <p>4 mg every 24 hours.</p>

Generalities

Selective antagonist of leukotriene receptors, active orally. It specifically inhibits the cysteinyl leukotriene receptor CysL1.

Risk in Pregnancy d

Adverse effects

Headache and abdominal pain.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. It is not the first choice in acute asthma attacks. It is not recommended for children under 6 years of age, nor during breastfeeding.

Interactions

None of clinical importance.

**NICOTINE**

Clue	Description	Indications	Route of administration and dosage
010.000.0082.00	PATCH Each 7 cm2 patch contains: Nicotine 36 mg. Containers with 7 patches.	Adjuvant in the treatment to eliminate the habit of tobacco.	Cutaneous. Adults: Smokers of more than 10 cigarettes a day:
010.000.0083.00	PATCH Each 15 cm2 patch contains: Nicotine 78 mg. Package with 7 patches.		Patch of 22 cm2 per day for 6 weeks. Patch of 15 cm2 per day for 2 weeks. Patch of 7 cm2 per day for 2 weeks. Smokers of less than 10 cigarettes a day:
010.000.0084.00	PATCH Each 22 cm2 patch contains: Nicotine 114 mg. Package with 7 patches.		Patch of 15 cm2 per day for 6 weeks. Patch of 7 cm2 per day for 2 weeks.

**Generalities**

The main alkaloid of tobacco products, it has been shown to be addictive and withdrawal is associated with characteristic withdrawal symptoms.

**Risk in Pregnancy C****Adverse effects**

Insomnia, nausea, slight stomach upset (dyspepsia, constipation), cough, throat irritation, dry mouth, myalgia and arthralgia.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug. Non-smokers, simultaneous use of another nicotine-containing product, pregnancy and lactation.

**Interactions**

Nicotine increases the levels of circulating catecholamines, therefore after stopping smoking it may be necessary to reduce doses of adrenergic blockers and increase doses of agonists.

**NINTEDANIB**

Clue	Description	Indications	Route of administration and dosage
010.000.6067.00	CAPSULE Each capsule contains: Nintedanib esylate 120.4 mg equivalent to 100.0 mg of Nintedanib Container with 60 capsules	Fibrosis Treatment Idiopathic Pulmonary.	Oral. Adults: 1 capsule of 150 mg every 12 hours.
010.000.6068.00	CAPSULE Each capsule contains: Nintedanib esylate 180.6 mg. equivalent to 150.0 mg. by Nintedanib Container with 60 capsules		

**Generalities**

Nintedanib is an oral tyrosine kinase inhibitor, which blocks platelet-derived growth factor (PDGFR), fibroblast growth factor (FGFR) and vascular endothelial growth factor (VEGFR) receptors related to proliferation and lung fibroblast migration. Nintedanib reduced the decline in FVC in patients with IPF, which is consistent with a reduction in disease progression; as well as a reduction in the risk of exacerbations associated with IPF.

**Risk in Pregnancy**

d

**Adverse effects**

Diarrhea, vomiting, nausea, abdominal pain, increased ALT, AST, ALKP, GGT, hyperbilirubemia, hypertension, loss of

appetite, weight loss.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

#### Interactions

No drug interactions are expected between nintedanib and CYP substrates or CYP inducers, as there is no evidence of inhibitory or inductive effects of CYP enzymes in preclinical studies.  
If coadministered with nintedanib, strong P-glycoprotein (P-gp) inhibitors (e.g., ketoconazole or erythromycin) may increase nintedanib exposure.

### OMALIZUMAB (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
010.000.4340.00	<p>INJECTABLE SOLUTION</p> <p>Each vial contains: Omalizumab 202.5 mg.</p> <p>Container with a vial and vial with 2 mL of diluent.</p>	<p>Persistent allergic asthma moderate to severe.</p> <p>Chronic spontaneous urticaria resistant to conventional treatment</p>	<p>Subcutaneous.</p> <p>Asthma Children over 6 years old and adults: The dose and administration interval depend on the basal IgE concentration (IU/mL) and weight.</p> <p>body (Kg); administer between 150 and 375 mg, every 2 or 4 weeks.</p> <p>In the case of the injectable solution in a vial, reconstitute the medication with 1.4 mL of the diluent (1.2 mL=150 mg of omalizumab).</p> <p>Chronic spontaneous urticaria Children over 12 years and adults The recommended dose is 300 mg by subcutaneous injection every four weeks. Some patients may achieve symptom control with 150 mg given every 4 weeks.</p> <p>In the case of the injectable solution in a vial, reconstitute the medication with 1.4 mL of the diluent (1.2 mL=150 mg of omalizumab).</p>

#### Generalities

It binds to IgE and prevents its binding to the high affinity FcεRI receptors, reducing the amount of free IgE available to initiate the immunological cascade of allergy.

#### Risk in Pregnancy

c

#### Adverse effects

Pain, erythema, pruritus and swelling at the injection site; headache, dizziness, drowsiness, paresthesia, syncope, postural hypotension, vasomotor crises, pharyngitis, cough, bronchospasm, nausea, diarrhea, dyspeptic signs and symptoms, urticaria, rash, pruritus, photosensitivity, allergic reactions.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Patients with autoimmune diseases mediated by immune complexes, renal or hepatic failure

#### Interactions

None of clinical importance.

### PIRPHENIDONE

Clue	Description	Indications	Route of administration and dosage
	<p>RELEASE TABLET PROLONGED</p>	<p>Fibrosis Treatment Idiopathic Pulmonary.</p>	<p>Oral.</p>

010.000.6069.00	Each tablet contains: Pirfenidone 600 mg  Container with 90 tablets.	Adults: 1800 mg per day. It is recommended to divide the daily dose every 12 hours.
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#### Generalities

It is a selective inhibitor of profibrotic cytokines such as TGF- $\beta$ , PDGF and EGF. Pirfenidone is indicated in those conditions that present with chronic fibrosis, associated with tissue damage of organs such as; Idiopathic Pulmonary Fibrosis.

#### Risk in Pregnancy

c

#### Adverse effects

Weight loss, anorexia, loss of appetite, insomnia, dizziness, headache, drowsiness, dysgeusia, hot flashes, dyspnea, cough, dyspepsia, nausea, diarrhea, vomiting, bloating, abdominal pain, constipation, flatulence, elevated liver enzymes ALT, AST, GGT, photosensitivity causing rash, pruritus, erythema, dry skin, myalgia, arthralgia, asthenia, upper respiratory tract infections, urinary tract infections.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. In patients with end-stage liver disease or severe renal failure (CrCL <30 mL/min).

Precautions: Minimize direct sun exposure. Avoid medications that cause photosensitivity.

Patients with liver failure. Patients with severe renal failure.

#### Interactions

Concomitant use with other drugs that have their metabolism in CYP1A2, theoretically, can modify the plasma concentrations of Pirfenidone, therefore a thorough evaluation of concomitant treatments with: fluoxetine, amiodarone, fluconazole, chloramphenicol, paroxetine, rifampicin, ciprofloxacin or propafenone is recommended. . It is not recommended to ingest simultaneously with grapefruit juice, as grapefruit may cause CYP1A2 inhibition.

## SALBUTAMOL

Clue	Description	Indications	Route of administration and dosage
010.000.0439.00	NEBULIZER SOLUTION  Each 100 mL contains: Salbutamol sulfate 0.5 g.  Container with 10 mL.	Bronchial asthma.  Bronchitis.	Inhalation.  Adults:  It is recommended to dilute 1 mL of the solution (500 $\mu$ g) in 2-3 mL of physiological saline solution to administer nebulization every 4-6 hours.  The concentration can be increased or decreased according to the results and the sensitivity of the patient.

#### Generalities

Agonist of  $\beta$ 2 adrenergic receptors of the lung, uterus and bronchial smooth muscle.

#### Risk in Pregnancy

c

#### Adverse effects

Nausea, tachycardia, tremors, nervousness, restlessness and palpitations. In addition to insomnia, bad taste in the mouth, oropharyngeal dryness, difficulty urinating, increase or decrease in blood pressure, rarely anorexia, paleness, chest pain.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and to sympathomimetic amines, cardiac arrhythmias, coronary insufficiency.

Precautions: In hyperthyroidism, diabetes mellitus or ketoacidosis. Do not increase the indicated dose as it may cause cardiac disorders.

#### Interactions

#### Adverse effects

Oropharyngeal irritation, tremor, headache, rash, edema.

It interacts and its use should be avoided in patients taking propranolol-type beta blockers as well as MAO inhibitors.

Adverse effects

Oropharyngeal irritation, tremor, headache, rash, edema.

**SALMETEROL**

Clue	Description	Indications	Route of administration and dosage
010.000.0441.00	AEROSOL SUSPENSION  Each gram contains: Salmeterol xinafoate equivalent to 0.330 mg. of salmeterol.  Inhaler container with 12 g for 120 doses of 25 µg.	Bronchodilator.	Inhalation.  Adults: 100 µg every 12 hours.  Children over 4 years: 50 µg every 12 hours.

## Generalities

Beta 2 adrenergic receptor agonist, with local action in the lung; In addition, it inhibits mediators derived from mast cells, therefore inhibiting the immediate and delayed response to the allergen.

## Risk in Pregnancy

c

## Adverse effects

Fine distal tremor, headache, palpitations, skin rash, angioedema, arthralgia

## Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, pregnancy, lactation and children under 4 years of age.

## Interactions

None of clinical importance.

**SALMETEROL, FLUTICASONE**

Clue	Description	Indications	Route of administration and dosage
010.000.0442.00	DUST  Each dose contains Salmeterol xinafoate equivalent to 50 µg of salmeterol. Fluticasone propionate 100 µg.  Package with inhaler device for 60 doses.	Obstructive disease chronicle.  Bronchial asthma.	Inhalation.  Adults and people over 4 years old:  One inhalation every 12 hours.
010.000.0447.00	DUST  Each dose contains: Salmeterol xinafoate equivalent to 50 µg. of salmeterol Fluticasone propionate 500 µg.  Package with inhaler device for 60 doses.		
010.000.0443.00	AEROSOL SUSPENSION  Each dose contains: Salmeterol xinafoate equivalent to 25 µg. of salmeterol. Fluticasone propionate 50 µg.  Package with inhaler device for 120 doses.		

## Generalities

Salmeterol is a long-acting (12 hours) selective  $\beta_2$ -agonist, which has a long side chain that binds to the exo-site of the receptor.

Fluticasone propionate by inhalation in the recommended doses has a potent anti-inflammatory action at the pulmonary level, resulting in a decrease in the intensity of symptoms and a decrease in the frequency of asthma exacerbations, without the side effects of systemically administered corticosteroids.

## Risk in Pregnancy

c

## Adverse effects

Oropharyngeal irritation, tremor, headache, rash, edema.



#### Contraindications and Precautions

Contraindications: Hypersensitivity to the components of the medication.

Precautions: In children and patients with pre-existing cardiovascular diseases, in addition to those who are predisposed to low serum potassium concentrations.

#### Interactions

Concomitant administration with  $\beta$ -blockers (selective or non-selective) should be avoided unless there is medical justification for their use.

## SILDENAFIL

Clue	Description	Indications	Route of administration and dosage
010.000.5845.00	<p>TABLET</p> <p>Each tablet contains: Sildenafil citrate equivalent to 20 mg. of sildenafil.</p> <p>Container with 90 tablets.</p>	Treatment of pulmonary arterial hypertension (PAH).	<p>Oral.</p> <p>Adults: 20 mg three times a day. The tablets can be taken with or without food.</p>

#### Generalities

Sildenafil is a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP), a phosphodiesterase type 5 (PDE5) that is the enzyme responsible for the generation of cGMP. In addition to the presence of this enzyme in the corpus cavernosum of the penis, PDE5 is also observed in the pulmonary vasculature, therefore Sildenafil increases cGMP within the pulmonary vascular smooth muscle cells, producing a relaxation effect.

#### Risk in Pregnancy

c

#### Adverse effects

Headache, flushing, diarrhea, pain in extremities and dyspepsia.

#### Contraindications and Precautions

Contraindications: Hypersensitivity to the active ingredient or some of the excipients.

Precautions: Mild and transient symptomatic hypotension. Patients should be aware that treatment with sildenafil may affect their ability to drive and operate machinery.

#### Interactions

The metabolism of Sildenafil is mainly mediated by cytochrome P450 isoforms CYP3A4 (main pathway) and 2C9 (secondary pathway). Therefore, inhibitors of this enzyme could reduce the clearance of sildenafil and inducers of these isoenzymes could increase the clearance of sildenafil. Coadministration of bosentan with sildenafil on a permanent basis results in a decrease in the systemic exposure of sildenafil. The combination of both drugs does not lead to clinically significant changes in blood pressure and was well tolerated in healthy patients. Concomitant administration of sildenafil with ritonavir is not recommended.

## TADALAFIL

Clue	Description	Indications	Route of administration and dosage
010.000.4312.02 010.000.4312.03	<p>TABLET</p> <p>Each tablet contains: Tadalafil 20 mg.</p> <p>Package with 28 tablets. Package with 56 tablets.</p>	Pulmonary arterial hypertension.	<p>Oral.</p> <p>Adults: 40 mg in a single dose, once a day.</p>

#### Generalities

Selective inhibitor of cyclic guanosine monophosphate (cGMP) specific for phosphodiesterase type 5 (PDE5).

#### Risk in Pregnancy

d

#### Adverse effects

permanent or temporary decrease in vision. Most affected individuals have had the following Generalities characteristics: age over 50 years, diabetes, high blood pressure, coronary heart disease, dyslipidemia or smoking.

It is a specific long-acting antimuscarinic (anticholinergic) agent. In the airways, the inhibition of

Tachycardia, hypotension, syncope, epistaxis, vomiting, eye pain, persistent erection or priapism. An association between the use of these medications and non-arteritic ischemic optic neuropathy, which causes

[REDACTED]

permanent or temporary decrease in vision. Most affected individuals have had the following Generalities characteristics: age over 50 years, diabetes, high blood pressure, coronary heart disease, dyslipidemia or smoking. It is a specific long-acting antimuscarinic (anticholinergic) agent. In the airways, the inhibition of

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug. Concomitant administration with nitric oxide, nitrate or organic nitrite donors. Ischemic optic neuropathy. Precautions: In case of a history of sudden decrease or loss of vision in one or both eyes, the risk in the use of the medication should be analyzed. If a sudden decrease in vision in one or both eyes occurs, you should stop taking the medication and consult your doctor.

**Interactions**

Enhances the hypotensive effects of nitrates used acutely or chronically.

**TERBUTALLINE**

Clue	Description	Indications	Route of administration and dosage
010.000.0432.00	INJECTABLE SOLUTION  Each mL contains: Terbutaline sulfate 0.25 mg.  Container with 3 vials.	Bronchial asthma, chronic bronchitis and pulmonary emphysema.	Subcutaneous.  Adults:  0.25 mg every 6-8 hours.

**Generalities**

It relaxes bronchial smooth muscle by binding to beta 2 adrenergic receptors. It also relaxes the uterine muscle.

**Risk in Pregnancy** b**Adverse effects**

Nervousness, tremors, headache, palpitations and tachycardia; irritative pharyngitis (in inhaled form); vomiting and nausea.

**Contraindications and Precautions**

Contraindications: Hypersensitivity to the drug.  
 Precautions: In diabetes mellitus, systemic arterial hypertension, hyperthyroidism, cardiac arrhythmias.

**Interactions**

Sustained systemic arterial hypertension may occur with MAO inhibitors. With beta adrenergic blockers (propranolol) the bronchodilator effect of the drug is inhibited.

**TIOTROPIUM BROMIDE**

Clue	Description	Indications	Route of administration and dosage
010.000.2262.00	DUST  Each capsule contains: Tiotropium bromide monohydrate equivalent to 18 µg of tiotropium.  Package with 30 capsules and inhaler device.	Chronic obstructive pulmonary disease.	Oral For inhalation Over 12 years and adults: 18 µg/day.
010.000.2263.00	DUST  Each capsule contains: Tiotropium bromide monohydrate equivalent to 18 µg of tiotropium.  Container with 30 capsules (replacement).		
010.000.6326.00	SOLUTION FOR INHALATION  Each mL contains: Tiotropium bromide monohydrate equivalent to 0.226 mg of Tiotropium.  Cardboard box with 4.0 mL cartridge (60 shots/ 30 doses) and dosing device.	Additional maintenance bronchodilator treatment in children with asthma, who remain symptomatic despite treatment at  with less corticosteroids, to improve symptoms and reducing exacerbations.	Oral inhalation  Children:  6 to 11 years Two shots (0.005 mg/dose) once a day, at the same time.

permanent or temporary decrease in vision. Most affected individuals have had the following Generalities characteristics: age over 50 years, diabetes, high blood pressure, coronary heart disease, dyslipidemia or smoking. It is a specific long-acting antimuscarinic (anticholinergic) agent. In the airways, the inhibition of

M3 muscarinic receptors relax bronchial smooth muscles.

Risk in Pregnancy c

Adverse effects

Dry mouth, cough and local irritation

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, to atropine and some derivatives such as ipratropium and oxitropium or to any of the components of this product.

Interactions

None of clinical importance

## ZAFIRLUKAST

Clue	Description	Indications	Route of administration and dosage
	TABLET		Oral.
	Each tablet contains: Zafirlukast 20 mg.	Treatment and prophylaxis of chronic bronchial asthma.	Adults: 20 mg every 12 hours.
010.000.4331.00	Package with 28 tablets.		
010.000.4331.01	Package with 30 tablets.		

Generalities

Selective antagonist of leukotriene D4 and E4 receptors

Risk in Pregnancy C

Adverse effects

Headache, nausea, vomiting, diarrhea, asthenia, abdominal pain, jaundice, lethargy.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, children under 12 years of age, acute treatment of asthma, breastfeeding.

Interactions

With erythromycin, theophylline decreases its plasma concentration, with aspirin its concentration increases, and the plasma concentration of warfarin increases.