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Group No. 20: Rheumatology and Traumatology

ALLOPURINOL

Clue	Description	Indications	Route of administration and dosage
010.000.2503.00 010.000.2503.01 010.000.2503.02	TABLET Each tablet contains: Allopurinol 100 mg Package with 20 tablets. Package with 50 tablets. Package with 60 tablets.	Primary gout or secondary. Hyperuricemia.	Oral. Adults: To prevent attacks: 100 mg/day, increase every 7 days by 100 mg, without exceeding the maximum dose of 800 mg. Drop 200 to 300 mg a day. Gout with tophi 400 to 600 mg/day.
010.000.3451.00	TABLET Each tablet contains: Allopurinol 300 mg Package with 20 tablets.		Children: Hyperuricemia secondary to malignant processes. From 6 to 10 years 300 mg/day in three doses. Children under 6 years: 50 mg three times a day.

Generalities

Reduces the production of uric acid by inhibiting the biochemical reactions that precede its formation.

Risk in Pregnancy

c

Adverse effects

Rash, nausea, vomiting, diarrhea, hepatotoxicity, peripheral neuritis, drowsiness, headache, agranulocytosis, aplastic anemia.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, breastfeeding.

Precautions: Cataracts or liver or kidney disease.

Interactions

Urine acidifiers promote the formation of kidney stones. Alcohol, thiazides and furosemide decrease their anti-gout effect. Xanthines increase serum theophylline. With anticoagulants the anticoagulant effect is potentiated, and with chlorpropamide the hypoglycemic effect. With antineoplastics, the potential to depress bone marrow increases.

COLCHICINE

Clue	Description	Indications	Route of administration and dosage
010.000.3409.00	TABLET Each tablet contains: Colchicine 1 mg Package with 30 tablets.	Acute attack of gout or its prevention.	Oral. Adults: Acute phase: 1 mg every one to two hours (maximum, 7 mg in 24 hours). Chronic phase 1 mg daily.

Generalities

It reduces leukocyte mobility, phagocytosis and lactic acid production, reduces the formation of urate crystal deposits and inflammation.

Risk in Pregnancy

d

Adverse effects

Aplastic anemia, agranulocytosis and with prolonged use non-thrombocytopenic purpura, peripheral neuritis, shock hematuria, oliguria, depression of the central nervous system, diarrhea, nausea and vomiting.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Liver dysfunction, heart disease, blood dyscrasias, kidney disease, genitourinary disorders, seniors.

Interactions

Alcohol and loop diuretics reduce the effectiveness of colchicine as a prophylactic, with phenylbutazone it can

increase the risk of leukopenia and thrombocytopenia and decreases the absorption of vitamin B12.

DICLOFENAC

Clue	Description	Indications	Route of administration and dosage
010.000.3417.00	CAPSULE OR DRAGEEE EXTENDED RELEASE Each dragee contains: Diclofenac sodium 100 mg Container with 20 capsules or dragees.	Inflammatory processes severe like: Rheumatoid arthritis. Ankylosing spondyloarthritis.	Oral. Adults: 100 mg every 24 hours. The maintenance dose must be adjusted to each patient. Maximum dose 200 mg/day.
010.000.5501.00	INJECTABLE SOLUTION Each vial contains: Diclofenac sodium 75 mg Container with 2 vials with 3 mL.	Spondylarthrosis. Osteoarthritis.	Deep intramuscular. Adults: One vial of 75 mg every 12 or 24 hours. Do not administer for more than two days.

Generalities

Anti-inflammatory, analgesic and antipyretic action due to inhibition of prostaglandin synthesis. It blocks leukocyte migration and alters immunological processes in tissues.

Risk in Pregnancy

b

Adverse effects

Nausea, vomiting, gastric irritation, diarrhea, dermatitis, depression, headache, vertigo, urinary difficulty, hematuria.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, lactation, coagulation disorders, asthma, peptic ulcer, liver and kidney failure, gastrointestinal bleeding, cardiovascular disease.

Recommendations: In the elderly and adults with low body weight. In prolonged treatment, monitor bone marrow, kidney and liver function.

Interactions

With acetylsalicylic acid, other NSAIDs, anticoagulants, adverse effects increase. It can increase the toxic effect of lithium methotrexate and digoxin. It inhibits the effect of diuretics and increases their potassium-saving effect. Alters insulin and oral hypoglycemic requirements.

KETOPROFEN

Clue	Description	Indications	Route of administration and dosage
010.000.2504.00	CAPSULE Each capsule contains: Ketoprofen 100 mg Container with 15 capsules.	Mild or moderate pain rheumatological or traumatic origin. Rheumatoid arthritis. Osteoarthritis. Dysmenorrhea.	Oral. Adults: 100 to 300 mg divided into three or four doses. Maximum dose 300 mg per day.

Generalities

It produces its anti-inflammatory, analgesic and antipyretic effect possibly by inhibiting the synthesis of prostaglandins.

Risk in Pregnancy

b

Adverse effects

Nausea, diarrhea, flatulence, peptic ulcer, anorexia, vomiting, hemorrhages, headache, dizziness, tinnitus, visual disorders, nephrotoxicity.

Contraindications and Precautions

Hypersensitivity to the drug, acetylsalicylic acid or other NSAIDs, peptic ulcer, liver or kidney dysfunction, coagulation disorders and breastfeeding.

Interactions

With oral anticoagulants the risk of bleeding increases, with acetylsalicylic acid, alcohol or steroids the risk of gastrointestinal side effects may increase.

MELOXICAM

Clue	Description	Indications	Route of administration and dosage
010.000.3421.00	ORAL SUSPENSION Each 100 mL contains: Meloxicam 0.150 g Container with 40 mL and 5 mL dosing pipette.	Rheumatoid arthritis. Osteoarthritis. Spondylitis. Gouty arthritis.	Oral. Adults and people over 12 years old: 15 mg every 24 hours. Children: Maximum dose: 0.25 mg/kg body weight/day.
010.000.3423.00	TABLET Each tablet contains: Meloxicam 15 mg Package with 10 tablets.	Acute and chronic non-rheumatic inflammatory conditions. Acute nonbacterial inflammatory processes of the upper airways.	

Generalities

Non-steroidal anti-inflammatory drug of the oxicam family, which selectively inhibits cyclooxygenase 2 (COX-2).

Risk in Pregnancy

c

Adverse effects

Hypersensitivity reaction, diarrhea, abdominal pain, nausea, vomiting and flatulence. It can cause bleeding due to erosion, ulceration and perforation in the gastrointestinal mucosa.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and acetylsalicylic acid, gastrointestinal irritation, peptic ulcer.

Interactions

Decreases the antihypertensive effect of ACE inhibitors and beta blockers. With cholestyramine its absorption decreases. With other NSAIDs, adverse effects increase. May increase the effects of anticoagulants and methotrexate. With diuretics it can cause acute renal failure.

METHOCARBAMOL

Clue	Description	Indications	Route of administration and dosage
010.000.3444.00	TABLET Each tablet contains: Methocarbamol 400 mg Package with 30 tablets.	Adjuvant in disorders Acute painful skeletal muscles.	Oral. Adults and kids older than 12 years old: 2 tablets every 6 hours.

Generalities

Relaxant of skeletal muscle, reduces the transmission of impulses from the spinal cord to skeletal muscle.

Risk in Pregnancy

c

Adverse effects

Dizziness, nausea, drowsiness, bradycardia, arterial hypotension, headache, fever and allergy manifestations.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, myasthenia gravis.

Interactions

With alcohol, anxiolytics, antipsychotics, opiates, tricyclic antidepressants and central nervous system depressants (CNS), increases CNS depression.

Naproxen

Clue	Description	Indications	Route of administration and dosage
	TABLET	Pain and inflammation	Oral.

010.000.3407.00	Each tablet contains: Naproxen 250 mg Package with 30 tablets.	acute. Rheumatoid arthritis. Osteoarthritis.	Adults: 500 to 1500 mg in 24 hours. Oral.
010.000.3419.00	ORAL SUSPENSION Each 5 mL contains: Naproxen 125 mg Container with 100 mL.	Ankylosing spondylitis. Tendinitis. Bursitis.	Children: 10 mg/kg body weight initial dose, followed by 2.5 mg/kg body weight every 8 hours. Maximum dose 15 mg/kg body weight/day.

Generalities

Its anti-inflammatory, analgesic and antipyretic effect is probably due to the inhibition of prostaglandin synthesis.

Risk in Pregnancy

b

Adverse effects

Nausea, gastric irritation, diarrhea, vertigo, headache, cross-hypersensitivity with aspirin and other non-inflammatory drugs. steroids.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, gastrointestinal bleeding, peptic ulcer, kidney and liver failure, lactation.

Interactions

It competes with oral anticoagulants, sulfonylureas and anticonvulsants for plasma proteins. It increases the action of insulins and hypoglycemics and antacids decrease their absorption.

PIROXICAM

Clue	Description	Indications	Route of administration and dosage
010.000.3415.00	CAPSULE OR TABLET Each capsule or tablet contains: Piroxicam 20 mg Package with 20 capsules or tablets.	Osteoarthritis. Rheumatoid arthritis. Ankylosing spondylitis. Acute gout. Post-surgical pain. Dysmenorrhea.	Oral. Adults: 20 mg daily, single dose taken after breakfast. In some cases the maintenance dose may be 10 mg per day.

Generalities

It inhibits the biosynthesis of prostaglandins, an action that depends on its inhibitory effect on cyclooxygenase.

Risk in Pregnancy

c

Adverse effects

Nausea, vomiting, diarrhea, skin rash, edema of extremities, leukopenia, gastrointestinal bleeding, hematuria, thrombocytopenia, aplastic anemia.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug or to other non-steroidal anti-inflammatories, severe renal failure, bone marrow depression, coagulation disorders, gastric ulcer and those over 65 years of age.

Interactions

Increases the effect of anticoagulants. It interacts with other bone marrow depressants, hepatotoxics and nephrotoxics, increasing adverse effects.

PREDNISONE

Clue	Description	Indications	Route of administration and dosage
	TABLET	Addison's disease.	Oral.

010.000.0472.00	Each tablet contains: Prednisone 5 mg Package with 20 tablets.	Asthma. Nephrotic syndrome. Diseases inflammatory. Autoimmune diseases.	Adults: 5 to 60 mg/day, single dose or every 8 hours. Sustaining dose according to the therapeutic response and subsequently gradually decreased until the lowest dose is reached according to the pharmacological effect. Maximum dose: 250 mg/day. Children: 0.5 to 2 mg/kg body weight/day or 25 to 60 mg/m ² body surface area, administered every 6 to 12 hours. Maximum dose: 40 mg/day. In nephrotic syndrome 80 mg/day.
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Generalities

Intermediate action glucocorticoid. It induces the transcription of RNA, 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 catabolism, delayed healing, growth retardation.

Contraindications and Precautions

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

Interactions

Increases the adverse effects of digitalis. Hypokalemia increases with thiazide diuretics, furosemide, and amphotericin B. With anticonvulsants, its hepatic biotransformation increases and with estrogens it decreases. With antacids, its intestinal absorption decreases.

SULINDACO

Clue	Description	Indications	Route of administration and dosage
010.000.5503.00	TABLET OR DRAGEE Each tablet or dragee contains: Sulindac 200 mg Package with 20 tablets or dragees.	Rheumatoid arthritis. Acute gouty arthritis. Bursitis. Ankylosing spondylitis. Tendinitis. Osteoarthritis.	Oral. Adults: One to two tablets every 24 hours. The dose may be reduced when symptoms subside.

Generalities

Its anti-inflammatory, analgesic and antipyretic effect is possibly due to inhibition of prostaglandin synthesis.

Risk in Pregnancy

b

Adverse effects

Nausea, vomiting, diarrhea, anorexia, peptic ulcer, palpitations, anemia, thrombocytopenia, dizziness, headache, tinnitus, rash.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and other NSAIDs, peptic ulcer, gastrointestinal bleeding, asthma, patients with compromised renal or cardiac dysfunction, systemic arterial hypertension, lactation.

Interactions

With anticoagulants the risk of bleeding increases. With other NSAIDs, gastrointestinal irritation increases.

ABATACEPT (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
010.000.5820.00	<p>INJECTABLE SOLUTION</p> <p>Each pre-filled syringe contains: Abatacept 125 mg.</p> <p>Package with 4 pre-filled syringes with 1 mL each (125 mg/mL).</p>	Active rheumatoid arthritis moderate to severe intensity refractory to DMARD treatment and one or more biological agents. It should be administered in combination with methotrexate.	<p>Subcutaneous.</p> <p>Adults: 125 mg weekly with or without loading dose.</p>

Generalities

Abatacept selectively modulates a key costimulatory signal that is necessary for full activation of CD28-expressing T cells.

Risk in Pregnancy

c

Adverse effects

Headache, dizziness, respiratory tract infections, rhinitis, herpes simplex, cough, urinary tract infections, hypertension, peripheral vasodilation, abdominal pain, dyspepsia, nausea, diarrhea, erythema, fatigue.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Patients with a history of recurrent or chronic infection. Failure to administer concurrently with live vaccines or coadministration of abatacept with immunosuppressive or immunomodulatory biologic agents could potentiate the effects of abatacept on the immune system.

Interactions

Concurrent use with Tumor Necrosis Factor blocking agents is not recommended.

ACEMETHACINE

Clue	Description	Indications	Route of administration and dosage
010.000.3405.01	<p>CAPSULE</p> <p>Each capsule contains: Acemetacin 60 mg</p> <p>Container with 28 capsules.</p>	<p>Pain and secondary inflammation to rheumatological conditions:</p> <p>Acute attack of gout.</p> <p>Bursitis.</p>	<p>Oral.</p> <p>Adults: 60 mg every 8 to 12 hours.</p>
010.000.3406.00	<p>RELEASE CAPSULE PROLONGED</p> <p>Each extended-release capsule contains: Acemetacin 90 mg</p> <p>Package with 14 prolonged release capsules.</p>	<p>Osteoarthritis.</p> <p>Post-trauma surgery.</p> <p>Tenosynovitis.</p>	<p>Oral.</p> <p>Adults: 90 mg every 12 to 24 hours.</p>
010.000.3406.01	<p>Package with 28 prolonged release capsules.</p>		

Generalities

Dual inhibitor of the cyclooxygenase system, preferentially inhibiting prostaglandins related to pain and inflammation, with little effect on physiological ones, which gives it a profile of great analgesic and anti-inflammatory power, with less renal, gastric and cardiovascular toxicity.

Risk in Pregnancy

c

Adverse effects

Nausea, vomiting, abdominal pain, diarrhea, loss of appetite.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, last trimester of pregnancy, lactation, acid-peptic disease.

Interactions

Digoxin, lithium salts, anticoagulants, corticosteroids, penicillin, acetylsalicylic acid, furosemide, potassium savers,

probenecid.

ADALIMUMAB (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION	Rheumatoid arthritis with inadequate response to Traditional DMARDs.	Subcutaneous.
	Each vial or prefilled syringe or prefilled syringe in autoinjector with 0.8 mL contains: Adalimumab 40 mg	Psoriatic arthritis.	Adults: Rheumatoid arthritis: 40 mg every 15 days. In combination with methotrexate.
010.000.4512.00	Package with a prefilled syringe.	Ankylosing spondylitis.	Psoriatic arthritis and ankylosing spondylitis: 40 mg every 15 days.
010.000.4512.01	Container with a vial and syringe.	Crohn's disease.	Active Crohn's disease: Induction:
010.000.4512.02	Package with a prefilled syringe in autoinjector.	Psoriasis.	160mg; apply 4 doses of 40 mg per day on two consecutive days, followed by 80 mg, two weeks later (day 16). Maintenance: Two weeks after finishing the induction period (day 30); apply 40 mg per day, every 2 weeks.
	Each 0.4 mL prefilled syringe or prefilled pen contains: Adalimumab		Psoriasis:
	40mg		Plaque psoriasis, moderate to severe intensity, apply 80 mg/day, followed after 7 days by 40 mg/day and then 40 mg every two days
010.000.4512.03	Pack with a prefilled syringe or prefilled pen		weeks.

Generalities

Blocks the action of tumor necrosis factor-alpha, a molecule that causes inflammation and destruction of the cells. joints.

Risk in Pregnancy

c

Adverse effects

Rhinitis, sinusitis, bronchitis, pneumonia, urinary tract infections, stomatitis, myalgia.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, pregnancy, lactation, tuberculosis, multiple sclerosis.

Interactions

None of clinical importance.

AZATHIOPRINE

Clue	Description	Indications	Route of administration and dosage
	TABLET	Immunosuppression in kidney transplant.	Oral.
	Each tablet contains: Azathioprine 50 mg	Systemic lupus erythematosus.	Adults:
010.000.3461.00	Package with 50 tablets.	Dermatomyositis.	As an immunosuppressant for transplant: 1 to 5 mg/kg body weight daily.
		Severe rheumatoid arthritis resistant to other treatments.	Other conditions: 3mg/kg body weight/day, dose is reduced according to response and tolerance.

Generalities

It alters purine metabolism and inhibits the synthesis of DNA, RNA and proteins.

Risk in Pregnancy

d

Adverse effects

Anorexia, nausea, vomiting, leukopenia, anemia, pancytopenia, infections, hemorrhages, hepatotoxicity,

hypersensitivity.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, previous treatment with alkylating agents.

Precautions: Liver dysfunction, systemic infections.

Interactions

With allopurinol, its biotransformation is inhibited and its adverse effects increase. It can antagonize the neuromuscular blockade produced by pancuronium.

BARICITINIB

Clue	Description	Indications	Route of administration and dosage
010.000.6185.00	<p>TABLET</p> <p>Each tablet contains: Baricitinib 2 mg</p> <p>Package with 28 tablets.</p>	Active rheumatoid arthritis moderate to severe refractory to DMARD treatment and one or more biological agents.	<p>Oral.</p> <p>Adults: 4 mg once a day.</p> <p>A dose of 2 mg once daily is appropriate for patients ≥75 years of age and may be appropriate for patients with a history of chronic or recurrent infections.</p>
010.000.6186.00	<p>TABLET</p> <p>Each tablet contains: Baricitinib 4 mg</p> <p>Package with 28 tablets.</p>		<p>A dose of 2 mg once daily for patients who have achieved sustained control of disease activity on 4 mg once daily and are eligible for dose reduction.</p> <p>Atopic dermatitis: 4 mg once a day.</p> <p>A dose of 2 mg once daily is appropriate for patients who maintain sustained control of the disease and in special populations (over 75 years of age, with a history of chronic or recurrent infections, with creatinine clearance between 30 and 60ml/min.)</p>

Generalities

Baricitinib is a selective and reversible inhibitor of Janus kinases (JAK) 1 and JAK2. Janus kinases (JAK) are enzymes that transduce intracellular signals from cell surface receptors for various cytokines and growth factors involved in hematopoiesis, inflammation, and immune function. Within the intracellular signaling pathway, JAKs phosphorylate and activate signal transducers and activators of transcription (STATs), which activate gene expression within the cell. Baricitinib modulates these signaling pathways by partially inhibiting the enzymatic activity of JAK1 and JAK2, thereby decreasing the phosphorylation and activation of STATs.

Risk in Pregnancy

c

Adverse effects

Upper respiratory tract infections, urinary tract infections, gastroenteritis, herpes simplex and shingles.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Baricitinib should be used with caution in patients with infections, hematologic abnormalities, and malignancies. Combination with biological FARNE or other Janus kinase (JAK) inhibitors is not recommended.

Interactions

The combination with biological DMARDs or other Janus kinase (JAK) inhibitors has not been studied. The use of baricitinib with potent immunosuppressive medicinal products such as azathioprine, tacrolimus or cyclosporine was limited in clinical studies of baricitinib, and a risk of additive immunosuppression cannot be excluded.

BETAMETHASONE

Clue	Description	Indications	Route of administration and dosage
010.000.2141.00	INJECTABLE SOLUTION Each vial or vial contains: Betamethasone sodium phosphate 5.3 mg equivalent to 4 mg of betamethasone. Container with a vial or a vial with 1 mL.	Inflammatory processes serious. Immunosuppression. Allergic reactions. Prevention of neonatal respiratory distress syndrome.	Intramuscular, intravenous or intra-articular. Adults: 0.5 to 9 mg/day. Pregnant: Intramuscular: 12 mg 36 to 48 hours before premature delivery. Children: 625 µg at 3.75 mg/ m2 body surface area/ day, administered every 12 hours.

Generalities

It stimulates the transcription of mRNA, with an increase in protein synthesis of enzymes and indirectly blocks phospholipase A2, inhibiting the synthesis of prostaglandins, thromboxanes and leukotrienes.

Risk in Pregnancy

c

Adverse effects

Gastric irritation, peptic ulcer, euphoria, insomnia, hypokalemia, hyperglycemia, increased susceptibility to infections, osteoporosis, glaucoma, high blood pressure. In children, growth and development can be arrested with chronic use.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, diabetes mellitus, glaucoma, serious infections, gastrointestinal irritation, osteoporosis, high blood pressure, Cushing's syndrome, myasthenia gravis, psychosis, seizures.

Interactions

Its effect decreases with: phenobarbital, phenytoin, rifampicin by increasing its biotransformation. Increases gastrointestinal irritation with non-steroidal anti-inflammatory drugs and alcohol. Increases hypokalemia produced by thiazides and furosemide.

CELECOXIB

Clue	Description	Indications	Route of administration and dosage
010.000.5505.00	CAPSULE Each capsule contains: Celecoxib 100 mg Container with 20 capsules.	Rheumatoid arthritis. Postoperative pain. Osteoarthritis.	Oral. Adult: One or two capsules every 12 or 24 hours.
010.000.5506.00	CAPSULE Each capsule contains: Celecoxib 200 mg Container with 10 capsules.		

Generalities

Analgesic and non-steroidal anti-inflammatory drug (NSAID) that selectively inhibits the enzyme cyclooxygenase-2 (COX-2). It is almost completely absorbed orally, is 97% bound to plasma proteins, is extensively biotransformed in the liver, and inactive metabolites are eliminated in bile (27%) and urine (57%). Less than 3% is excreted in urine. Half-life of 11 hours.

Risk in Pregnancy

c

Adverse effects

Abdominal pain, diarrhea, dyspepsia, flatulence, nausea, lower back pain, edema, headache, vertigo, rhinitis, pharyngitis and sinusitis. Melena, hypertension, anemia and allergic reactions occur in less than 2% of patients, and gastrointestinal perforation, hepatitis, arrhythmias and kidney damage occur in less than 0.1%.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and non-steroidal anti-inflammatory drugs.

Precautions: Use under strict medical supervision and do not exceed the higher recommended doses, especially

in patients with liver failure, heart and kidney failure and a history of acid-peptic disease.

Interactions

Increases the adverse effects of other NSAIDs and anticoagulants. Counteracts the effect of antihypertensives.

CERTOLIZUMAB PEGOL (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
010.000.5795.00	INJECTABLE SOLUTION Each prefilled syringe contains: Certolizumab pegol 200 mg Package with 2 syringes prefilled with 1 mL.	Crohn's disease. Rheumatoid arthritis with inadequate response to traditional DMARDs. Axial spondyloarthritis . Psoriatic arthritis . Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.	Subcutaneous. Adults: Crohn's disease: 400 mg initially (given in 2 injections of 200 mg each) and in weeks 2 and 4; subsequently, 400 mg every 4 weeks. Rheumatoid arthritis: 400 mg initially (given in 2 injections of 200 mg each) and in weeks 2 and 4; thereafter, 200 mg every two weeks. In combination with methotrexate. For maintenance doses, 400 mg every 4 weeks can be considered. In combination with methotrexate. Axial spondyloarthritis: 400 mg (given in 2 subcutaneous injections of 200 mg each) initially and in weeks 2 and 4, thereafter the maintenance dose is 200 mg every two weeks or 400 mg every 4 weeks. Psoriatic arthritis: 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at weeks 2 and 4; subsequently 200 mg every two weeks. For maintenance doses, 400 mg every 4 weeks can be considered. Plaque psoriasis: Adults: Induction dose: The recommended induction dose is 400 mg (given in 2 subcutaneous injections of 200 mg each) initially (week 0) and in weeks 2 and 4. Maintenance dose: 200 mg every 2 weeks. A dose of 400 mg every 2 weeks may be considered for patients with insufficient response. Assess response after 16 weeks of treatment

Generalities

Certolizumab pegol has a high affinity for human TNF γ to which it binds with a dissociation constant (KD) of 90 pM. TNF γ is a key pro-inflammatory cytokine that plays a critical role in inflammatory processes. Certolizumab pegol selectively neutralizes TNF γ (IC90 of 4 ng/mL for *in vitro* inhibition of human TNF γ in a cytotoxicity assay with murine fibrosarcoma L929 cells) but does not neutralize lymphotoxin γ (TNF γ).

Risk in Pregnancy

b

Adverse effects

Bacterial and viral infections, eosinophilic disorders, leukopenia including neutropenia, lymphopenia, headaches including migraine, hypertension, nausea, hepatitis including increased liver enzymes, rash,

pyrexia, pain, asthenia, pruritus, injection site reactions.

Contraindications and Precautions

Contraindications: Hypersensitivity to the biological. Active tuberculosis or other serious infections such as sepsis or opportunistic infections. Moderate to severe heart failure.

Precautions: Patients should be closely monitored for signs and symptoms of infections including tuberculosis before, during and after treatment with Certolizumab pegol. Because the elimination of Certolizumab pegol can take up to 5 months, monitoring should continue throughout this period.

Before starting treatment with Certolizumab pegol., all patients should be evaluated for active or inactive (latent) tuberculosis. This evaluation should include a detailed medical history for patients with a personal history of tuberculosis or possible previous exposure to patients with active tuberculosis and previous and/or current immunosuppressive treatment. Appropriate screening tests should be performed, e.g. tuberculin skin test and chest x-ray, in all patients (applying local recommendations). It is recommended to note the performance of these tests on the patient alert card. Clinicians are reminded of the risk of false negative tuberculin skin testing, especially in patients who are severely ill or immunocompromised.

HBV carriers who require treatment with Certolizumab pegol should be carefully monitored for any signs and/or symptoms of active HBV infection during treatment and for months following completion of treatment.

Patients treated with Certolizumab pegol can be vaccinated, except with live vaccines. No data are available on the response to live vaccines or on secondary transmission of infections by live vaccines in patients receiving Certolizumab pegol. Live vaccines should not be co-administered with Certolizumab pegol.

Interactions

Based on a population pharmacokinetic analysis, concomitant treatment with methotrexate, corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics showed no effects on the pharmacokinetics of certolizumab pegol.

The combination of Certolizumab pegol and anakinra or abatacept is not recommended.

Coadministration of Certolizumab pegol with methotrexate had no significant effect on the pharmacokinetics of methotrexate. In a comparison between trials, the pharmacokinetics of certolizumab pegol appeared similar to those previously observed in healthy subjects.

COLLAGEN-POLYVINYLPIRROLIDONE

Clue	Description	Indications	Route of administration and dosage
010.000.3999.00 010.000.3999.01	<p>INJECTABLE SOLUTION</p> <p>Each milliliter contains: Collagen-polyvinylpyrrolidone 141.3 mg equivalent to 8.33 mg of collagen</p> <p>Container with 1.5 mL. Container with 4 mL.</p>	<p>Bone consolidation in fractures.</p> <p>Pseudoarthrosis and osteoarthrosis.</p>	<p>Intralesional.</p> <p>Children, adolescents and adults:</p> <p>Fractures: 1.5 mL weekly, for 8 weeks.</p> <p>Pseudoarthrosis: 1.5 mL weekly, during 10 weeks.</p> <p>Osteoarthrosis: Intra-articular 1.5 mL weekly for 5 weeks.</p>

Generalities

Collagen-polyvinylpyrrolidone acts at the level of fibroblasts and macrophages, modulating collagen metabolism.

Risk in Pregnancy

c

Adverse effects

None of clinical interest, except burning during application.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions. Consider the use of collagen-polyvinylpyrrolidone on areas of infection, if necessary, apply systemic antibiotic therapy.

Interactions

None of clinical interest.

DEXAMETHASONE

Clue	Description	Indications	Route of administration and dosage
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010.000.4241.00	INJECTABLE SOLUTION	Serious inflammatory processes, such as: Rheumatoid arthritis. Bursitis. Ankylosing spondylitis. Systemic lupus erythematosus. Osteoarthritis. Synovitis.	Intravenous, intramuscular, intra-articular or intralesional. Adults: Initial dose ranges from 0.5 to 16 mg daily intramuscularly or intravenously. Since the required dosage is variable, it must be individualized according to the type of disease and the response.
	Each vial or vial contains: Dexamethasone sodium phosphate equivalent to 8 mg dexamethasone phosphate. Container with a vial or vial with 2 mL.		

Generalities

Anti-inflammatory and anti-allergic glucocorticoid. Suppresses the immune response and stimulates the bone marrow.

Risk in Pregnancy

C

Adverse effects

They depend on the dose and duration. Euphoria, insomnia, hypertension, edema, glaucoma, peptic ulcer, increased appetite, hyperglycemia, delayed wound healing, acne, muscle weakness, hirsutism, adrenal insufficiency.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, disseminated fungal infections.

Precautions: Peptic ulcer, systemic arterial hypertension, osteoporosis, diabetes mellitus, thromboembolism.

Interactions

Phenobarbital, phenytoin and rifampin decrease their effect by biotransformation. Indomethacin and aspirin increase the risk of peptic ulcer. Thiazide diuretics and furosemide promote the development of hypokalemia.

ETANERCEPT

Clue	Description	Indications	Route of administration and dosage
010.000.4510.00	INJECTABLE SOLUTION	Rheumatoid arthritis with inadequate response to traditional DMARDs. Ankylosing spondylitis. Psoriasis.	Subcutaneous. Adults: Rheumatoid arthritis: 25 mg twice a week. 50 mg per week. In combination with methotrexate.
	Each vial contains: Etanercept 25 mg Package with 4 vials, 4 syringes with 1 mL of diluent and 8 pads		
010.000.4510.01	Package of 4 prefilled syringes with 0.5 mL.		Ankylosing spondylitis: 25 mg twice a week. 50 mg per week.
010.000.4511.00	INJECTABLE SOLUTION		Psoriasis: Start with 50 mg twice a week until week 12 and from week 13 continue with 50 mg per week until remission is achieved, for a maximum period of 24 weeks.
	Each container contains: Etanercept 50 mg Package with 2 vials, 2 syringes with 1 mL of diluent.		
	Package with 2 syringes prefilled with 1 mL.		
010.000.4511.01	Package with 2 pens prefilled with 1 mL.		Children: Rheumatoid arthritis: 0.4 mg/kg body weight up to a maximum of 25 mg, twice a week, each dose separated by 3 or 4 days.
010.000.4511.02			Psoriasis 0.8 mg/kg body weight to a maximum of 50 mg, once a week for a maximum of 24 weeks.

Generalities

It is a dimeric fusion protein of the human tumor necrosis factor p75 Fc receptor. It inhibits Tumor Necrosis Factor, interrupting the inflammatory cascade characteristic of Rheumatoid Arthritis. In the case of Psoriasis, it inhibits Tumor Necrosis Factor, inhibiting the proliferation of keratinocytes.

Risk in Pregnancy

C

Adverse effects

Fever, pruritus, urticaria, thrombositopenia, anemia leukopenia, pancytopenia, seizures, angioedema. Aplastic anemia, erythema, pruritus, pain or swelling at the injection site. Antibody formation.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, sepsis, infections, blood dyscrasias.
Precautions: In patients with: history of previous blood dyscrasias, with pre-existing or recent onset CNS demyelinating disease, with congestive heart failure, history of recurrent or chronic infections. Do not administer live vaccines concurrently with etanercept.

Interactions

None of clinical importance.

ETORICOXIB

Clue	Description	Indications	Route of administration and dosage
010.000.5699.00	COMPRESSED Each tablet contains: Etoricoxib 90 mg Package with 28 tablets.	Acute treatment of pain in rheumatoid arthritis.	Oral. Adults and people over 18 years of age: 90 mg every 24 hours.

Generalities

Oral selective inhibitor of cyclooxygenase-2.

Risk in Pregnancy

c

Adverse effects

Edema/fluid retention; dizziness, headache; palpitations; HTA; gastrointestinal disorders (abdominal pain, flatulence, heartburn), diarrhea, dyspepsia, epigastric discomfort, nausea; ecchymosis; asthenia/fatigue, flu-like syndrome; increased ALT and AST.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Patients with congestive heart failure (NYHA classification II-IV), established ischemic heart disease, peripheral arterial disease and/or cerebral vascular disease (including patients recently undergoing coronary revascularization procedures or angioplasty).

Precautions: Its use is not recommended in patients with advanced kidney disease. Caution should be exercised when initiating use in dehydrated patients, and the possibility of fluid retention, edema, or hypertension should be taken into account when used in patients with preexisting edema, hypertension, or heart failure. It should be used with caution in patients who have previously suffered acute asthmatic attacks, urticaria or rhinitis precipitated by salicylates or non-specific cyclooxygenase inhibitors.

Interactions

Warfarin: Standard monitoring of international normalized ratio prothrombin time values should be performed when treatment is initiated or changed to etoricoxib. Rifampicin: Co-administration of both substances decreased the area under the curve of plasma concentrations of etoricoxib by 65%. Methotrexate: Monitoring for methotrexate-related toxicity should be considered when etoricoxib at doses greater than 90 mg and methotrexate are used concurrently. Diuretics, Angiotensin Converting Enzyme Inhibitors (ACEIs and Angiotensin II Antagonists (AII)): NSAIDs, including selective COX-2 inhibitors, may decrease the antihypertensive effect of diuretics, ACEIs and AIIIs. The combination should be administered with caution, especially in elderly patients. Lithium: Non-selective NSAIDs and selective COX-2 inhibitors may increase plasma lithium concentrations. Acetylsalicylic acid (ASA): May be used concurrently with low doses of ASA used as cardiovascular prophylaxis. Concomitant administration of low doses of ASA and etoricoxib increases the incidence of gastrointestinal ulcers or other complications. Oral contraceptives: An increased concentration of ethinyl estradiol should be taken into account when choosing an appropriate oral contraceptive for use at the same time. Hormone Replacement Therapy: An increase in estrogen concentration should be taken into account when choosing postmenopausal hormone therapy for simultaneous use.

GOLIMUMAB (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION Each pre-filled pen contains:	Rheumatoid Arthritis with inadequate response to traditional DMARDs.	Subcutaneous. Adults

010.000.5950.00	Golimumab 50 mg Package with a pre-filled pen with 0.5 mL.	Psoriatic arthritis Ankylosing spondylitis Ulcerative colitis.	Rheumatoid Arthritis: 50 mg once a day month. It must be administered in combination with methotrexate. Psoriatic Arthritis: 50 mg once a month. Alone or in combination with methotrexate. Ankylosing spondylitis: 50 mg once a month.
010.000.6154.00	INJECTABLE SOLUTION Each pre-filled pen contains: Golimumab 100 mg Package with a 1 mL pre-filled pen.		ulcerative colitis Adults: Patients with body weight less than 80 kg. It is administered as an initial dose of 200 mg, followed by 100 mg weekly 2, and subsequently 50 mg every 4 weeks. Patients with body weight greater than or equal to 80 kg. It is administered as an initial dose of 200 mg followed by 100 mg in the week 2, and subsequently 100 mg every 4 weeks.

Generalities

Human IgG1k monoclonal antibody produced using a murine hybrid cell line with DNA technology recombinant.

Risk in Pregnancy

b

Adverse effects

Upper respiratory tract infections, bacterial and viral infections, anemia, leukopenia and thrombocytopenia, dizziness, paresthesias, hypertension, constipation, alopecia, pyrexia, reaction at the injection site.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Patients with a clinically significant active infection.

Precautions: Infections, active tuberculosis, hepatitis B virus reactivation, congestive heart failure, neurological events. Live viral vaccines should not be administered during use of Golimumab.

Interactions

No specific studies have been carried out.

SODIUM HYALURONATE

Clue	Description	Indications	Route of administration and dosage
010.000.6019.00	INJECTABLE SOLUTION Each prefilled syringe contains: Sodium hyaluronate 25 mg Package with a 2.5 mL prefilled syringe.	Adjuvant to treatment of knee osteoarthritis.	Intra-articular. Adults: 25 mg per week for 5 consecutive weeks, this constitutes one treatment course.

Generalities

Hyaluronic acid is a polysaccharide present in the connective tissue that makes up the joints, such as articular cartilage, the synovial membrane and synovial fluid. Proteoglycans are also a fundamental part of articular cartilage. They bind to hyaluronic acid, forming macromolecular aggregates, which in turn combine with reticular structures of type II collagen, giving rise to the matrix of articular cartilage, which plays an important role in : water retention, resistance to load and joint movement.

Risk in Pregnancy

c

Adverse effects

Pain after application, swelling, urticaria-like rash, pruritus, edema, flushing, sensation of heat, sensation of heaviness at the injection site.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: The result of the experimental research indicates that no teratogenesis, mutagenesis, or carcinogenesis was evident.

Interactions

In general it does not present. However, the use of local antiseptics such as chlorhexidine and quaternary ammonium salts including benzalkonium chloride should be avoided as they may cause precipitation of hyalurate sodium.

SODIUM HYALURONATE

Clue	Description	Indications	Route of administration and dosage
060.833.0361.01	Sterile elasto-viscose solution for intra-articular application Each ml contains: Sodium hyaluronate 10 mg Box or container with syringe with 2 ml.	Help with the replacement of synovial fluid after arthrocentesis. Hyaluronic acid is a normal component of synovial fluid and plays a central role in maintaining the internal physiological environment of the joint.	According to what the staff indicates capable.
060.833.0429.00	Sodium hyaluronate 15 mg Box or container with syringe with 2 ml.		
060.833.0445.00	Sodium hyaluronate 10 mg Package with 1 syringe prefilled with 60mg/6ml. sterile		

INDOMETHACIN

Clue	Description	Indications	Route of administration and dosage
010.000.3412.00 010.000.3412.01	SUPPOSITORY Each suppository contains: Indomethacin 100 mg Container with 6 suppositories. Container with 15 suppositories.	Anti-inflammatory in acute and chronic articular or periarticular processes. Utero-inhibitor.	Rectal. Adults: 100 mg twice a day. Oral.
010.000.3413.00	CAPSULE Each capsule contains: Indomethacin 25 mg Container with 30 capsules.		Adults: 25 to 50 mg three times a day.

Generalities

It produces its anti-inflammatory, analgesic and antipyretic effect by inhibiting the synthesis of prostaglandins.

Risk in Pregnancy

B/D in third trimester

Adverse effects

Nausea, vomiting, epigastric pain, diarrhea, headache, vertigo, hypersensitivity reactions, gastrointestinal bleeding.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and NSAIDs, breastfeeding, gastrointestinal bleeding, epilepsy, Parkinson's disease, psychiatric disorders, bronchial asthma, children under 14 years of age and anorectal conditions.

Interactions

It increases the toxicity of lithium, reduces the effects of furosemide and increases the effect of anticoagulants and hypoglycemics.

INFlixIMAB (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
010.000.4508.00	INJECTABLE SOLUTION The vial with lyophilisate contains: Infliximab 100 mg Container with a vial bottle with	Rheumatoid arthritis with inadequate response to traditional DMARDs. Psoriatic arthritis. Ulcerative colitis.	Intravenous infusion over 2 hours. Rheumatoid arthritis: initial dose of 3 mg/Kg, followed by 3 mg/Kg at 2 and 6 weeks, and then every 8 weeks. In combination with Methotrexate.

	freeze-dried and instructive.	Ankylosing spondylitis. Psoriasis.	Ankylosing spondylitis and psoriatic arthritis: 5 mg/kg, followed by 5 mg/kg at 2 and 6 weeks, and then every 8 weeks weeks. Psoriasis: initial dose of 5 mg/Kg, followed by 5 mg/Kg at 2 and 6 weeks, and then every 8 weeks. Ulcerative colitis: initial dose of 5 mg/Kg, followed by 5 mg/Kg at 2 and 6 weeks, and then every 8 weeks. Administer diluted in intravenous solutions packaged in glass bottles.
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Generalities

Monoclonal antibody to tumor necrosis factor alpha. It has a volume of distribution of 3 L and a half-life of 8-9.5 days.

Risk in Pregnancy

b

Adverse effects

Abdominal pain, nausea and vomiting are common. Hypersensitivity reactions, fungal and opportunistic infections, lupus syndrome and worsening heart failure.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, severe congestive heart failure.
Precautions: Mild heart failure, active infection, tuberculosis and seizure disorders.

Interactions

Corticosteroids increase the volume of distribution.

LEFLUNOMIDE

Code	Description	Indications	Route of administration and dosage
010.000.4514.00	COMPRESSED Each tablet contains: Leflunomide 20 mg Package with 30 tablets.	Active rheumatoid arthritis in adults.	Oral. Adults: Start with a loading dose of 100 mg/day for three days. Maintenance dose: 20 mg/day.
010.000.4515.00	COMPRESSED Each tablet contains: Leflunomide 100 mg Package with 3 tablets.		

Generalities

The active metabolite of leflunomide, M1 (A771726), slows the development of the cell cycle of target cells in different phases. M1 inhibits T cell proliferation and DNA synthesis *in vitro* after stimulation by mitogens. It inhibits the mitogen-stimulated proliferation of human peripheral blood mononuclear cells (PBMCs) as well as the proliferation of transformed human and murine cell lines in a dose-dependent manner.

Risk in Pregnancy

x

Adverse effects

Hepatotoxicity, sepsis, immunosuppression, leukopenia, pancytopenia, Stevens-Johnson syndrome.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and the components of the formula. Severe liver failure. Severe immunodeficiency (HIV/AIDS). Bone marrow dysplasia., Serious or chronic uncontrolled infections.
Precautions: Kidney failure, blood dyscrasias, bone marrow suppression.

Interactions

Administration of cholestyramine or activated charcoal reduces plasma concentrations of M1. Vaccination with live vaccines is not recommended. When the administration of a live vaccine is being considered

After stopping treatment with leflunomide, its long half-life must be taken into account.

ORPHENADRINE

Clue	Description	Indications	Route of administration and dosage
010.000.3443.00	INJECTABLE SOLUTION Each vial contains: Orphenadrine citrate 60 mg Container with 6 vials of 2 mL.	muscle contracture post-traumatic.	Intramuscular. Adults: 60 mg every 12 hours, as needed.

Generalities

Reduces the transmission of impulses from the spinal cord to skeletal muscle.

Risk in Pregnancy

c

Adverse effects

Dry mouth, palpitations, urinary retention, headache, orthostatic hypotension, blurred vision, constipation, nausea, vomiting.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, peptic ulcer, glaucoma, pyloric or duodenal obstruction, prostatic hypertrophy, myasthenia gravis, severe liver or kidney disease.

Interactions

With alcohol and CNS depressants, depression of the nervous system increases. Adverse effects increase with antimuscarinics.

SECUKINUMAB

Clue	Description	Indications	Route of administration and dosage
010.000.6080.00	INJECTABLE SOLUTION Each pre-filled pen contains: Secukinumab 150 mg Package with two pre-filled pens with 1 mL (150 mg/mL).	Adult patients active with ankylosing spondylitis inadequate response, intolerance, or contraindication to conventional therapy, non-steroidal anti-inflammatory drugs or tumor necrosis factor inhibitors.	Ankylosing spondylitis: 150 mg per subcutaneous injection, which is initially administered at 0 weeks, 1, 2 and 3 and then from week 4, on a monthly basis.

Generalities

Secukinumab is a fully human IgG1 monoclonal antibody that selectively binds and neutralizes the proinflammatory cytokine IL-17A. Secukinumab inhibits the interaction of IL-17A with the IL-17 receptor, which is expressed on various cell types including keratinocytes.

Risk in Pregnancy

b

Adverse effects

Rhinopharyngitis, Pharyngitis, Rhinitis, Sinusitis, Tonsillitis, Oral herpes, Oral candidiasis, Neutropenia, Conjunctivitis, Diarrhea, Tinea pedis, Otitis externa.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Infections: Mild to moderate upper respiratory tract such as nasopharyngitis without the need to interrupt treatment.

Mucocutaneous infections due to Candida. Crohn's disease: Exacerbations of the disease, in some cases severe, have been observed in patients with active Crohn's disease. Vaccines:

Live vaccines should not be administered simultaneously with secukinumab.

Interactions

Live vaccines should not be administered simultaneously with Secukinumab. The formation of some CYP450 enzymes is suppressed by increased cytokine levels during chronic inflammation. Therefore, a clinically significant effect on CYP450 substrates cannot be excluded as a narrow therapeutic index, where the dose is adjusted individually (e.g. warfarin). Secukinumab has been administered with methotrexate and/or corticosteroids in arthritis studies (including psoriatic arthritis and ankylosing spondylitis) in which no

observed no interaction.

INTRA-ARTICULAR SOLUTION

Clue	Description	Indications	Route of administration and dosage
010.833.0346.00	Sterile elasto-viscose solution of intra-articular application. Each ml contains: Hylan: 8.0 mg Container with 2 ml syringe.	Synovial fluid substitute.	According to what is indicated by the trained staff.

Generalities

Substitute for auxiliary synovial fluid in the treatment of osteoarthritis of the knee and hip, which do not respond to pharmacological treatment and cannot undergo surgery.

Adverse effects

Pain and edema.

Contraindications and Precautions

Infected or intensely inflamed wounds or in patients suffering from skin diseases or infections in the injection application area.

TOCILIZUMAB (In Catalog II program)

Clue	Description	Indications	Route of administration and dosage
010.000.4513.00	INJECTABLE SOLUTION Each vial contains: Tocilizumab 80 mg Container with vial bottle with 4 mL.	Active rheumatoid arthritis of moderate to severe intensity refractory to DMARD treatment and to one or more biological agents. It should be administered in combination with methotrexate.	Intravenous. Adults: Rheumatoid arthritis: 8 mg/kg of body weight, every 4 weeks, combination with methotrexate, in
010.000.4516.00	INJECTABLE SOLUTION Each vial contains: Tocilizumab 200 mg Container with vial bottle with 10 mL.	Systemic juvenile idiopathic arthritis (sJIA) refractory to traditional DMARD treatment or in combination with methotrexate.	Systemic Juvenile Idiopathic Arthritis (sJIA): 8 mg/kg (patients with a body weight \geq 30 kg) or 12 mg/kg (patients with a body weight <30 kg), administered every 2 weeks.
010.000.6047.00	INJECTABLE SOLUTION Each prefilled syringe contains: Tocilizumab 162 mg Package with 4 prefilled syringes with 0.9 mL each.		Subcutaneous Adults: 162 mg once a week.

Generalities

Tocilizumab is a humanized, anti-human monoclonal antibody of the immunoglobulin G1 (IgG1) subclass directed against soluble and membrane interleukin 6 (IL-6) receptors. Tocilizumab specifically binds to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R), and has been shown to inhibit the signaling cascade mediated by sIL-6R and mIL-6R.

Risk in Pregnancy x

Adverse effects

Upper respiratory tract infections, injection site reaction, abdominal pain, gastritis, skin rash, pruritus, urticaria, headache, dizziness, increased levels of hepatic transaminases, hypertension, leukopenia, neutropenia, hypercholesterolemia, cough, dyspnea, conjunctivitis .

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug

Precautions: Tocilizumab treatment should not be initiated in patients with serious active infections and should be discontinued if a patient develops a serious infection. Should be used with caution in patients with

previous history of intestinal ulceration or diverticulitis. An examination to detect latent tuberculosis should be performed prior to starting treatment. Live and attenuated vaccines should not be administered concurrently with Tocilizumab. If an anaphylactic reaction or other severe hypersensitivity reaction occurs, Tocilizumab administration should be stopped immediately and permanently discontinued. It is necessary to evaluate the risk-benefit profile in patients with a history, high risk or demyelinating pathologies. Neutrophils, platelets, and liver transaminases should be monitored and treatment modifications made in case of alteration of normal parameters.

Interactions

Medications that are metabolized through CYP450 3A4, 1A2, or 2C9 (e.g., atorvastatin, calcium channel blockers, theophylline, warfarin, phenytoin, cyclosporine, or benzodiazepines) should be monitored as the doses of these products may require be adjusted to maintain their therapeutic effect.

TOFACITINIB

Clue	Description	Indications	Route of administration and dosage
010.000.6111.01	<p>TABLET</p> <p>Each tablet contains:</p> <p>Tofacitinib citrate equivalent to 5 mg tofacitinib</p> <p>Package with 56 tablets.</p>	<p>Active rheumatoid arthritis of moderate to severe intensity refractory to DMARD treatment and to one or more biological agents. It should be administered in combination with methotrexate</p>	<p>Oral.</p> <p>Adults:</p> <p>5 mg administered twice daily, in combination with methotrexate.</p>

Generalities

Tofacitinib is a potent and selective inhibitor of the JAK family of kinases with a high degree of selectivity against other kinases in the human genome. Tofacitinib inhibits JAK1, JAK2, JAK3 and to a lesser extent tyrosine kinase 2. Inhibition of JAK1 and JAK3 by Tofacitinib blocks signaling through receptors that contain the common gamma chain for many cytokines including IL-2, -4, -7, -9, -15 and -21. These cytokines are for the activation, proliferation and function of lymphocytes and the inhibition of their signaling can cause the modulation of multiple aspects of the immune response. Furthermore, inhibition of JAK1 will cause attenuation of signaling by additional pro-inflammatory cytokines, such as IL-6 and type 1 interferons. At higher exposures, inhibition of erythropoietin signaling may occur through inhibition of erythropoietin signaling, by JAK2

Risk in Pregnancy

c

Adverse effects

Serious upper respiratory tract infections, headache, nasopharyngitis, diarrhea, shingles, and pneumonia

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Patent or laboratory evidence of immunodeficiency syndromes, severe active infections, severe liver dysfunction.

Precautions: Tofacitinib should be used with caution in patients who may be at increased risk of gastrointestinal perforation. No dose adjustment is required in patients with mild or moderate renal dysfunction, nor in patients with mild liver dysfunction. The use of tofacitinib in combination with biological DMARDs should be avoided. selective modulators of co-stimulation and potent immunosuppressants such as azathioprine and cyclosporine.

Interactions

Because tofacitinib is metabolized by CYP3A4, interaction with drugs that inhibit or induce CYP3A4 is likely. Coadministration with Methotrexate (15-25 mg MTX once weekly) had no effect on the pharmacokinetics of Tofacitinib. In patients with rheumatoid arthritis (RA), the oral clearance of Tofacitinib does not vary over time indicating that Tofacitinib does not normalize CYP enzymatic activity in patients with RA. Therefore, coadministration with Tofacitinib is not expected to cause clinically relevant increases in the metabolism of CYP substrates in patients with RA.