Update date: February 1, 2024

Group No. 10: Hematology

ACENOCUMAROL

Clue	Description	Indications	Route of administration and dosage
	TABLET Each tablet contains: Acenocoumarol 4 mg. Package with 20 tablets. Package with 30 tablets.	Anticoagulant.	Oral. Adults: Initial: 12 mg. Second day: 8 mg. Third day: 4 mg. Subsequent: 2 to 8 mg per day, depending on the prothrombin time result.
010.000.0624.00			
010.000.0624.01			

Generalities

Oral anticoagulant that inhibits the synthesis of vitamin K-dependent coagulation factors (factor II, VII, IX and X.).

Risk in Pregnancy

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Adverse effects

Increased serum transaminases, bleeding.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, lactation, tuberculosis.

Interactions

Barbiturates, carbamazepine, cholestyramine, hormonal contraceptives, glutethimide and rifampin decrease the anticoagulant effect.

TRANEXAMIC ACID

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION Each mL of sterile solution for intravenous injection contains: Tranexamic acid 100 mg. CBP vehicle 1 mL Box with 10 vials of 5 mL Box with 10 vials of 10 mL	Indicated in prevention and treatment of bleeding due to general or local fibrinolysis	Route of administration: Intravenous The dosage of injectable tranexamic acid, 100 mg/mL should be according to actual body weight; consider dose adjustment in obese patients. Postpartum hemorrhage (PPH) Intravenous loading dose: 1,000 mg over 20 minutes, repeat the same dosage if bleeding continues after 30 minutes or rebleeding occurs within 24 hours. Administration should be carried out as soon as possible, preferably <3 hours.
010.000.7021.00 010.000.7021.01			
	INJECTABLE SOLUTION Each vial contains: Tranexamic acid 500 mg cbp vehicle 5mL Container with five vials of 5 mL each		Hyperfibrinolysis-induced hemorrhage 15 mg/kg or 1 g every 6 to 8 hours. Continue until bleeding stops or laboratory tests indicate treatment can be stopped. To reduce postoperative bleeding and blood transfusions after cardiac surgery Loading or bolus dose: 10 mg/kg (range 2.5 mg/kg to 100 mg/kg), infused over 20-30 minutes. Maintenance dose: 1 mg/kg for 10-12 hours (range 0.25 mg/kg/h to 4 mg/kg/h, for 1 to 12 hours). Hemorrhage associated with trauma Intravenous loading dose: 1,000 mg over 10 minutes, followed by 1,000 mg over the next 8 hours
010.000.7033.00			

Generalities

Tranexamic acid is a competitive inhibitor of plasminogen activation and, at much higher concentrations, a non-competitive inhibitor of plasmin, that is, it has actions similar to aminocaproic acid. Tranexamic acid is approximately 10 times more potent in vitro than aminocaproic acid.

Risk in Pregnancy

Reproduction studies in mice, rats and rabbits have revealed no evidence of impaired fertility or adverse effects on the fetus due to tranexamic acid.

There are no adequate and well-controlled studies in pregnant women. However, it is known that tranexamic acid
crosses the placenta and appears in the umbilical cord blood in concentrations approximately equal to the maternal concentration. Because animal reproduction studies are not always predictive of human response, this medication should be used during pregnancy only if clearly needed.

Adverse effects

Gastrointestinal disturbances (nausea, vomiting, diarrhea) may occur but disappear when the dose is reduced.
Allergic dermatitis, dizziness and hypotension have been reported occasionally. Hypotension has been reported when intravenous injection is too rapid. To avoid this response, the solution should not be injected at more than 1 mL per minute.
Thromboembolic events (deep vein thrombosis, pulmonary embolism, cerebral thrombosis, acute renal cortical necrosis, and central retinal artery and vein obstruction) have been reported rarely in patients receiving tranexamic acid for indications other than prevention of hemorrhage in patients. with hemophilia.
Seizures, chromatopsia, and visual impairment have also been reported. However, due to the spontaneous nature of reporting of medical events and the lack of controls, the true incidence and causal relationship between the drug and the event cannot be determined.

Contraindications and Precautions

Tranexamic acid injection is contraindicated in the following cases:
Patients with acquired defective color vision, since this prevents measuring an endpoint that should be followed as a measure of toxicity.

Patients with subarachnoid hemorrhage. Anecdotal experience indicates that cerebral edema and cerebral infarction may be caused by tranexamic acid injection in such patients.
In patients with active intravascular coagulation.
In patients with hypersensitivity to tranexamic acid or any of its ingredients.
Focused areas of retinal degeneration have developed in cats, dogs, and rats after administration of oral or intravenous tranexamic acid at doses between 250 to 1,600 mg/kg/day (six to 40 times the recommended human dose) for six days to one year. The incidence of such lesions has varied from 25% to 100% of treated animals and has been dose related. At lower doses, some lesions appear to be reversible.

Limited data in cats and rabbits showed retinal changes in some of these animals at doses as low as
126 mg/kg/day (only about three times the recommended human dose) given for several days to up to two weeks.

No retinal changes have been reported or found in eye examinations performed in patients treated with tranexamic acid for weeks or months during clinical studies.

However, visual abnormalities, often poorly characterized, represent the most frequently reported post-marketing adverse reaction in Sweden. For patients who must be treated continuously for several days,
An ophthalmological examination that includes visual acuity, color vision, fundus and visual fields is recommended before
before starting treatment and at regular intervals during the course of treatment. Tranexamic acid should be discontinued if changes are found in the results of said ophthalmological examination.
Seizures have been reported associated with treatment with tranexamic acid, particularly in patients who received it.
during cardiovascular surgery and in patients who inadvertently received tranexamic acid into the neuraxial system.

Cases of allergic reaction have been reported with the use of intravenous tranexamic acid, including anaphylaxis or anaphylactoid reaction, suggesting a causal relationship.
The dose of tranexamic acid injection should be reduced in patients with renal impairment due to the risk of
accumulation (see dosage and administration).
Ureteral obstruction due to clot formation has been reported in patients with upper urinary tract hemorrhage treated with tranexamic acid injection.

Cases of venous and arterial thrombosis or thromboembolism have been reported in patients treated with tranexamic acid injection. In addition, cases of obstruction of the central retinal artery and central retinal vein have been reported.
Patients with a history of thromboembolic disease may be at increased risk of arterial or venous thrombosis.
Tranexamic acid injection should not be administered concomitantly with factor IX complex concentrates or anti-inhibitory coagulant concentrates, as it may increase the risk of thrombosis.
Patients with disseminated intravascular coagulation (DIC) who require treatment with tranexamic acid injection should be under the close supervision of a physician with experience in the treatment of this disorder.

Interactions

No interaction studies have been performed between tranexamic acid injection and other drugs.

PHYTOMENADIONE

Clue	Description	Indications	Route of administration and dosage
	SOLUTION OR EMULSION INJECTABLE	Hyprothrombinemia due to:	Intramuscular.
	Each vial contains: Phytomenadione 10 mg.	Poisoning by oral anticoagulants.	Newly born: 2 mg after birth.
010.000.0626.00 010.000.0626.01	Container with 3 vials of 1 mL. Container with 5 vials of 1 mL.	Prevention of hemorrhage in neonates.	Adults:

010.000.1732.00 010.000.1732.01	SOLUTION OR EMULSION INJECTABLE Each vial contains: Phytomenadione 2 mg. Container with 3 vials of 0.2 mL. Container with 5 vials of 0.2 mL.	Hepatocellular disease. Vitamin K deficiency due to prolonged parenteral nutrition.	10 to 20 mg every 6 to 8 hours. Maximum dose 50 mg/day. Children: 2 to 10 mg/day.

Generalities

Promotes hepatic formation of vitamin K-dependent coagulation factors.

Risk in Pregnancy C

Adverse effects

Hemolysis, jaundice, indirect hyperbilurubinemia, diaphoresis, sensation of chest tightness, vascular collapse.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Erythrocyte glucose-6-phosphate dehydrogenase deficiency, myocardial infarction, active or recent cerebral hemorrhage.

Interactions

Decreases the effect of oral anticoagulants.

FERROUS FUMARATE

Clue	Description	Indications	Route of administration and dosage
010.000.1701.00	TABLET Each tablet contains: Ferrous fumarate 200 mg. equivalent to 65.74 mg. of elemental iron. Package with 50 tablets.	Prevention and treatment of iron deficiency.	Oral. Adults: 200 mg three times a day Prevention: 200 mg/day
010.000.1702.00	ORAL SUSPENSION Each mL contains: Ferrous fumarate 29 mg. equivalent to 9.53 mg of elemental iron. Container with 120 mL.		Oral. Children: 3 mg/kg body weight /day, divided into three doses. Prophylaxis: 5 mg/kg body weight/day. Divide into three doses. Premature: 1 to 2 mg/kg body weight/day, divided into three doses. Administer with food.

Generalities

Provides elemental iron which is the essential component for the synthesis of hemoglobin.

Risk in Pregnancy A

Adverse effects

Abdominal pain, nausea, vomiting, heartburn, constipation.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.
Precautions: Peptic ulcer, regional enteritis, ulcerative colitis, liver damage, gastritis, hemochromatosis, hemosiderosis, non-ferrodeficient anemias.

Interactions

Antacids, vitamin E and cholestyramine decrease its gastrointestinal absorption. With vitamin C its absorption increases.

MENADIONA

Clue	Description	Indications	Route of administration and dosage
	TABLET	Complex deficiency prothrombin.	Oral.
	Each tablet contains:		Adults:
	Menadione 2 mg.		2 to 4 mg every 24 hours.
010.000.1733.00	Package with 20 tablets.		Children:
			1 to 2 mg every 24 hours.

Generalities

Water-soluble substance that, like phytonadione, promotes the hepatic synthesis of prothrombin and the VII; IX and X of blood coagulation.

Risk in Pregnancy

TO

Adverse effects

Nausea, vomiting, hypersensitivity reactions, hemolysis, jaundice.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. In patients with severe hepatic failure, glucose-6-phosphate dehydrogenase deficiency and bile duct obstruction or fistula.
Precautions: During the last trimester of pregnancy it can promote jaundice in the newborn.

Interactions

With broad-spectrum antimicrobials, salicylates and sulfonamides, vitamin K requirements increase.

FERROUS SULFATE

Clue	Description	Indications	Route of administration and dosage
	TABLET	Prevention and treatment of iron deficiency.	Oral.
	Each tablet contains: Sulfate dried ferrous		Adults:
	approximately 200 mg equivalent to 60.27 mg. of elemental iron.		Prophylaxis 200 mg/day for 5 weeks. Treatment: 100 mg three times a day for weeks, gradually increasing to 200 mg three times a day, and according to the patient's need.
010.000.1703.00	Package with 30 tablets.		
	SOLUTION		
	Each mL contains:		Children:
	Ferrous sulfate heptahydrate 125 mg equivalent to 25 mg. of elemental iron.		Prophylaxis 5 mg/kg/day, every 8 hours for 5 weeks.
			Treatment 10 mg/kg/day, divided into three doses.
010.000.1704.00	Dropper container with 15 mL.		It should be administered after food.

Generalities

Essential for the formation of hemoglobin, myoglobin and oxidative enzymes. Controls the translation and stability of RNA delivery courier.

Risk in Pregnancy

TO

Adverse effects

Abdominal pain, nausea, vomiting, diarrhea, constipation, heartburn, darkening of urine and stool. Chronic administration produces hemochromatosis.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, acid peptic disease, hepatitis, hemosiderosis, hemochromatosis, non-iron deficiency anemias and repeated transfusions.

Interactions

Tetracyclines and antacids reduce its absorption and vitamin C increases it. Deferoxamine decreases the effects of iron.

ABCIXIMAB

Clue	Description	Indications	Route of administration and dosage
010.000.4247.00	INJECTABLE SOLUTION Each vial contains: Abciximab 10 mg. Container with a vial (10 mg/5mL).	Assistant in prevention of ischemic heart complications in patients with angioplasty or percutaneous transluminal coronary atherectomy.	Intravenous or intravenous infusion. Adults: 0.25 mg/kg body weight at baseline, followed by 0.125 µg/kg body weight/min for 12 hours in infusion.

Generalities

It is a chimeric monoclonal antibody Fab fragment, directed against GP II b / III a receptors, with an inhibitory effect on platelet aggregation.

Risk in Pregnancy

c

Adverse effects

Back pain, nausea, vomiting, arterial hypotension, headache, pain at the puncture site, thrombocytopenia.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Active internal bleeding. Hemorrhagic diathesis. Uncontrolled severe arterial hypertension. Arteriovenous malformation or aneurysm. History of cerebral vascular event, intracranial or intraspinal surgery.

Interactions

Concomitant use of abciximab with any thrombolytic increases the risk of bleeding.

AMINOCAPROIC ACID

Clue	Description	Indications	Route of administration and dosage
010.000.4237.00	INJECTABLE SOLUTION Each vial contains: Aminocaproic acid 5 g. Container with a 20 mL vial.	Hyperfibrinolysis.	Intravenous infusion. Adults: Initial: 5 g/hour, continue with 1 to 1.25 g/hour until bleeding is controlled. Maximum dose: 30 g/day. Children: 100 mg/kg body weight/hour, continue with 33.3 mg/kg body weight /hour until the bleeding is controlled. Maximum dose: 18 g/day. Administer diluted in intravenous solutions packaged in glass bottles.

Generalities

It inhibits plasminogen activating substances and to a lesser extent blocks antiplasmin activity by inhibiting fibrinolysis.

Risk in Pregnancy

c

Adverse effects

Dizziness, nausea, diarrhea, malaise, headache, hypotension, bradycardia, arrhythmias, tinnitus, nasal obstruction, lacrimation, erythema, generalized thrombosis.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and evidence of active intravascular coagulation.

Interactions

Estrogens and oral contraceptives increase the likelihood of thrombosis. Its use together with antifibrinolytic agents in the management of subarachnoid hemorrhage increases the presence of hydrocephalus and cerebral ischemia.

ANTITHROMBIN III

Clue	Description	Indications	Route of administration and dosage
010.000.5340.00	INJECTABLE SOLUTION The vial with lyophilisate contains: Antithrombin III 500 IU. Container with vial and vial with 10 mL of diluent.	Deficiency of antithrombin III. Thromboembolism. Hypercoagulability.	Intravenous. Adults: Initial: Units required = body weight in kg x (100-actual antithrombin III activity in percent). Maintenance: According to the severity of the patient and the coagulation response obtained. Children: 40-60 IU/kg body weight per day up to 250 IU/kg body weight per day depending on the coagulation response. Administer diluted in intravenous solutions packaged in glass bottles.

Generalities

Blood coagulation inhibitor.

Risk in Pregnancy

c

Adverse effects

Allergic reactions, chest pain, fever, headache, nausea, vomiting.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Interactions

Its effect is increased with heparin.

APIXABAN

Clue	Description	Indications	Route of administration and dosage
010.000.5731.00 010.000.5731.01	TABLET Each tablet contains: Apixaban 2.5 mg. Package with 20 tablets. Package with 60 tablets.	Primary prevention of Cerebral vascular events related to non-valvular atrial fibrillation. Prevention of venous thromboembolism in adult patients after elective total knee and hip replacement.	Oral. Adults. 5 mg twice a day. 2.5 mg twice daily in patients with at least two of the following characteristics: age ÿ80 years; body weight ÿ 60 kg; or serum creatinine ÿ1.5 mg/dl (133 mmol/L).
010.000.5732.00 010.000.5732.01	TABLET Each tablet contains: Apixaban 5 mg. Package with 20 tablets. Package with 60 tablets.		2.5 mg administered twice daily in patients with severe kidney damage (creatinine clearance 15-29 mL/min). For patients after elective total knee and hip replacement. Oral. Adults: 2.5 mg administered twice daily orally. The initial dose should be taken between 12 and 24 hours after surgery.

Generalities

Apixaban is a potent, reversible, direct and highly selective oral inhibitor of factor Xa. It does not require antithrombin III for antithrombotic activity. Apixaban inhibits free and clot-bound factor Xa and prothombinase activity.

Apixaban has no direct effects on platelet aggregation but rather indirectly inhibits thrombin-induced platelet aggregation. By inhibiting factor Xa, apixaban prevents both thrombin formation and thrombus formation.

Risk in Pregnancy

c

Adverse effects

Epistaxis, hematuria, hematomas, ocular bleeding and gastrointestinal bleeding.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.
Precautions: Clinically significant active bleeding, liver disease associated with coagulopathy, injury or pathology with a significant risk of bleeding, concomitant treatment with any other anticoagulant agent.
As with other anticoagulants, patients taking apixaban should be carefully monitored for any signs of bleeding.

No dose adjustment is necessary during concomitant treatment with a strong CYP3A4 and P-glycoprotein inducer (such as rifampin, phenytoin, carbamazepine, phenobarbital, or St. John's wort). However, the
Strong CYP3A4 and P-gp inducers should be coadministered with caution.

Interactions

The use of apixaban is not recommended in patients receiving concomitant systemic treatment with strong CYP3A4 and P-glycoprotein inhibitors such as azole antifungals (e.g. ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (e.g. ritonavir).).

APROTININ

Clue	Description	Indications To	Route of administration and dosage
010.000.5246.00	INJECTABLE SOLUTION Each mL contains: Aprotinin 10,000 IUK. Container with vial with 50 mL (500,000 UIK).	reduce the bleeding and the need for blood transfusion in cardiac surgery.	Intravenous. Adults: 10,000 UIK as proof. If there are no adverse reactions in the next 10 minutes, administer a dose of 2 million IUK. for 30 minutes prior to sternotomy. Continue with infusion of 500,000 UIK/hour. Administer diluted in intravenous solutions packaged in glass bottles.

Generalities

Inhibitor of serum and tissue proteases (trypsin, plasmin and kallikrein) that participate in the coagulation and fibrinolytic systems, through the formation of aprotinin-proteinase junctions and anti-inflammatory effect due to inhibition of the release of IL-6.

Risk in Pregnancy b

Adverse effects

Myocardial injury in patients with previous coronary pathology, thrombotic phenomena; mediastinitis; temporary kidney dysfunction and occasionally allergic reactions.

Contraindications and Precautions

Contraindications: Hypersensitivity to meat, because the medicine is prepared from bovine lung.

Interactions

With heparin it increases clotting time and can enhance the neuromuscular blocking effect of succinylcholine.

SODIUM BEMIPARIN

Clue	Description	Indications of	Route of administration and dosage
010.000.5634.00	INJECTABLE SOLUTION Each prefilled syringe contains: Bemiparin sodium 3,500 IU. Package with 2 syringes prefilled with 0.2 mL.	Prevention of the thromboembolic disease in patients in with knee surgery.	Subcutaneous. Adults: 3,500 IU, 2 hours before or 6 hours after surgery and maintain treatment for 7 to 10 days every 24 hours.

Generalities

In animal experimental models, bemiparin has shown antithrombotic activity and a moderate hemorrhagic effect. In humans, bemiparin confirms its antithrombotic efficacy and does not produce, at the recommended doses, a significant prolongation of global coagulation tests.

Risk in Pregnancy NE

Adverse effects

Ecchymosis at the injection site. Hematoma at the injection site and pain. Hemorrhagic complications (skin, mucous membranes, gastrointestinal and urogenital tract wounds). Moderate and transient elevation of transaminase levels (ASAT, ALAT) and g-GT. Anaphylactic reactions (nausea, vomiting, fever, dyspnea, bronchospasm, glottis edema, hypotension, urticaria, pruritus). Severe thrombocytopenia (type II).

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.
Precautions: Cases of liver or kidney failure, uncontrolled arterial hypertension, history of gastroduodenal ulcer, thrombocytopenia, nephrolithiasis and/or urethrolithiasis, vascular disease of the choroid and retina, or any other organic lesion susceptible to bleeding, or in patients undergoing spinal anesthesia. or epidural and/or lumbar puncture.

Interactions

Concomitant administration of bemiparin with the following drugs is not recommended: vitamin K antagonists and other anticoagulants, acetylsalicylic acid, other salicylates and non-steroidal anti-inflammatory drugs, ticlopidine, clopidogrel and other antiplatelet agents, systemic glucocorticoids and dextran. Drugs that increase serum potassium concentration should only be taken under special medical supervision.

FACTOR VIII ANTI-INHIBITOR COAGULANT COMPLEX

Clue	Description	Indications	Route of administration and dosage
010.000.4218.00	INJECTABLE SOLUTION The vial with lyophilisate contains: Anti-factor VIII inhibitor coagulant complex 500 U FEIBA. Human plasma protein 200-600 mg. Container with a vial with lyophilisate and a bottle with 20 mL of diluent.	Hemorrhage in patients with antifactor inhibitors VIII and antifactor IX.	Intravenous (2 U FEIBA/kg/min). Children and adults: Guidance dose according to severity and clinical response: 50-100 U/kg, without exceeding a daily dose of 200 U/kg.
010.000.4219.00	INJECTABLE SOLUTION FEIBA anti-factor VIII inhibitor coagulant complex 1000 U. Human plasma protein 400-1200 mg. Container with a vial with lyophilisate and a bottle with 20 mL of diluent.		

Generalities

Inhibitor of serum and tissue proteases (trypsin, plasmin and kallikrein) that participate in the coagulation and fibrinolytic systems, through the formation of aprotinin-proteinase junctions and anti-inflammatory effect due to inhibition of the release of IL-6.

Risk in Pregnancy b

Adverse effects

Myocardial injury in patients with previous coronary pathology, thrombotic phenomena; mediastinitis; temporary kidney dysfunction and, occasionally, allergic reactions.

Contraindications and Precautions

Contraindications: Hypersensitivity to meat, because the medicine is prepared from bovine lung

Interactions

With heparin it increases clotting time and can enhance the neuromuscular blocking effect of succinylcholine.

HUMAN PROTHROMBIN COMPLEX

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION Each vial with lyophilisate contains: Human coagulation factor II 200-480 IU Human coagulation factor VII 100-250 IU Coagulation factor IX Human 200-310 IU Human coagulation factor X 220-600 IU Protein C 150-450 IU Protein S 120-380 IU Total proteins 60-140 mg	Treatment and prophylaxis preoperative bleeding in acquired deficiency of prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required.	Intravenous. Adults: It is recommended to administer a single dose. The dose and duration of replacement therapy depend on the severity of the disorder, the location and extent of bleeding, and the clinical condition of the patient.
010.000.6101.00	Package with a vial with lyophilisate, a vial with 10 mL of diluent and a transfer device.	preoperative treatment and prophylaxis of bleeding in congenital deficiency of any of the vitamin K-dependent coagulation factors when specific purified products of the coagulation factor are not available	
	INJECTABLE SOLUTION Each vial with lyophilisate contains: Human coagulation factor II 400-960 IU Human coagulation factor VII 200-500 IU Human coagulation factor IX 400-620 IU Human Coagulation Factor X 440-1200 IU Protein C 300-900 IU Protein S 240-760 IU Total proteins 120-280 mg.		
010.000.6102.00	Package with a vial with lyophilisate, a vial with 20 mL of diluent and a transfer device.		

Generalities

The prothrombin complex is a concentrate of plasma origin that contains the four coagulation factors dependent on vitamin K in its hepatic synthesis (II, VII, IX and anticoagulant role: protein C and protein S which provides a hemostatic balance of coagulation factors and inhibitors.

Risk in Pregnancy

c

Adverse effects

Rarely it can lead to the formation of circulatory antibodies that inhibit one or more factors of the prothrombin complex, manifesting as a poor clinical response. Allergic or anaphylactic reactions and an increase in body temperature may rarely occur. Risks of thromboembolic episodes and headache.

Contraindications and Precautions

Contraindications: Hypersensitivity to the components of the biological.
Precautions: Known allergy to heparin or history of heparin-induced thrombocytopenia, increased risk of Disseminated Intravascular Coagulation (DIC) and high risk of thrombosis.

Interactions

Prothrombin complexes neutralize the effect of treatment with vitamin K antagonists (oral anticoagulants of the coumarin and indandionic type), interactions with other medicinal products are unknown. You should not use products during administration.

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COAGULABLE HUMAN PROTEIN CONCENTRATE

Clue	Description	Indications	Route of administration and dosage
010.000.4248.00	SOLUTION Each vial I contains: Concentrated human coagulable proteins 80 to 120 mg. Each vial II contains: Human thrombin 1800 to 2200 IU. Calcium chloride 11.2 to 12.4 mg. Package with two vials (I and II) with 2 mL each, two previously assembled syringes and an air tube with a 0.2 µm filter.	Auxiliary hemostatic seal surgical in procedures.	Topical. Adults and children: Application on the surface of the wound to coagulate.
010.000.4279.00	SOLUTION Each vial I contains: Concentrated human coagulable proteins 200 to 300 mg. Each vial II contains: Human thrombin 4500 to 5500 IU. Calcium chloride 28 to 31 mg. Package with two vials (I and II) with 5 mL each, two previously assembled syringes and an air tube with a 0.2 µm filter.		
010.000.4282.00	SOLUTION Each vial 1 contains: Total Fibrinogen Lyophilisate Concentrate 57.5-116 mg. Fibrinogen (human plasma protein fraction) 32.5-57.5 mg. Factor XIII 20-40 U. Each vial 2 contains: Bovine lung aprotinin 500 KIU. Corresponding to 0.28 PEU in 0.5 mL. Each vial 3 contains: Thrombin total dry substance 2.45- 5.55 mg. Human plasma protein fraction with thrombin activity 200-300 IU. Each 4 vial contains: Calcium chloride dehydrated 14.7 mg in 2.5 mL. Package with vials 1 and 2 and vials 3 and 4 linked through a transfer device.		
010.000.4283.00	SOLUTION Each mL of reconstituted solution contains: Fibrinogen 70-110 mg Plasmafibronectin 2- 9 mg Factor XIII 10-50 IU Plasminogen 0-120 µg Aprotinin 3,000 IUK Thrombin 4 IU or Thrombin 500 IU Calcium chloride 40 µmol Package with a 1.0 mL vial with fibrinogen lyophilisate with 70-110 mg, plasmafibronectin with 2-9 mg, factor XIII with 10-50 IU and plasminogen with 0-120 ÿg; one vial of aprotinin 3000 UIK in 1 mL;		

	a vial with 4 IU thrombin lyophilisate; a vial with 500 IU thrombin lyophilisate; a vial with calcium chloride with 40 ýmol in 1 mL and container with two assembled syringes and accessories for reconstitution and application.		
010.000.4284.00	SOLUTION Each mL of reconstituted solution contains: Fibrinogen 70-110 mg. Plasmafibronectin 2- 9 mg. Factor XIII 10-50 IU. Plasminogen 0-120 µg. Aprotinin 3,000 IUK. Thrombin 4 IU. or Thrombin 500 IU. Calcium chloride 40 µmol. Container with a 2.0 mL vial with lyophilized fibrinogen with 140-220 mg, plasmafibronectin with 4-18 mg, factor XIII with 20-100 IU and plasminogen with 0-240 ÿg; one vial of aprotinin 6000 UIK in 2 mL; a vial with 8 IU thrombin lyophilisate; a vial with 1000 IU thrombin lyophilisate; a vial with calcium chloride with 80 ÿmol in 2 mL and a container with two assembled syringes and accessories for reconstitution and application.		
010.000.4288.00	SOLUTION Each vial 1 contains: Total fibrinogen lyophilisate. Concentrated 345-698 mg. Fibrinogen (human plasma protein fraction) 195-345 mg. Factor XIII 120-240 U. Each vial 2 contains: Bovine lung aprotinin 3,000 KIU. corresponding to 1.67 PEU in 3.0 mL. Each vial 3 contains: Thrombin dry substance total 14.7-33.3 mg. Human plasma protein fraction. with activity thrombin 1,200-1,800 IU. Each 4 vial contains: Calcium chloride dehydrated 44.1 mg. in 7.5 mL. Package with vials 1 and 2 and vials 3 and 4 joined via a transfer device.		
010.000.6031.00	SOLUTION Each mL of reconstituted solution contains: Human Fibrinogen 91 mg (as coagulable protein) Bovine or synthetic aprotinin 3,000 UIK Human thrombin 500 IU Calcium chloride 40 µmol Package with a bottle with lyophilized Fibrinogen (91 mg), a vial with 1 mL of solution of Bovine or synthetic aprotinin (3000		

	UIK) as a diluent; a vial with lyophilized Thrombin (500 IU) and a vial with 1 mL of calcium chloride solution (40 µ mol) as diluent. Equipment for reconstitution and application.			
010.000.6032.00	SOLUTION Each mL of reconstituted solution contains: Human Fibrinogen 91 mg (as coagulable protein) Bovine or synthetic aprotinin 3,000 IUK Human thrombin 500 IU Calcium chloride 40 µmol Package with a bottle with lyophilized Fibrinogen (182 mg), a vial with 2 mL of bovine or synthetic Aprotinin solution (6000 UIK) as a diluent; a vial with lyophilized Thrombin (1000 IU) and a vial with 2 mL of solution of calcium chloride (80 µ mol) as diluent. Equipment for reconstitution and application.			
010.000.6033.00	SOLUTION Each mL of reconstituted solution contains: Human Fibrinogen 91 mg (as coagulable protein) Bovine or synthetic aprotinin 3,000 UIK Human Thrombin 500 IU Calcium chloride 40 µmol Package with a bottle with lyophilized Fibrinogen (455 mg), a vial with 5 mL of bovine or synthetic Aprotinin solution (15,000 UIK) as a diluent; a vial with lyophilized Thrombin (2500 IU) and a vial with 5 mL of calcium chloride solution (200 µ mol) as diluent. Equipment for reconstitution and application.			

Generalities

Hemostatic agent formed by a cryoprecipitate of coagulable proteins, mainly fibrinogen, and thrombin, which when combined, generate fibrin and activated factor VIII. The result is the formation of a layer of hemostatic gel on the tissues injured by the surgery.

Risk in pregnancy NE

Adverse effects

Hypersensitivity reactions to the components of the compound.

Contraindications and precautions

Contraindications: Surgery involving the meninges.
Precautions: Secondary allergic reactions may occur to the application of the compound.

Interactions

None of clinical importance.

DABIGATRAN ETEXYLATE

Clue	Description	Indications	Route of administration and dosage
	CAPSULE Each capsule contains: Dabigatran etexilate mesylate	Prevention of venous thromboembolic events in adults undergoing elective total blood replacement surgery hip and knee.	Oral. Adults: Patients with moderate insufficiency: renal

010.000.5551.00 010.000.5551.01	equivalent to 75 mg. dabigatran etexilate Container with 30 capsules. Container with 60 capsules.		Hip surgery, 75 mg, 1-4 hours after surgery and continue thereafter with 150 mg each 24 hours for 28 to 35 days. Knee surgery, 75 mg, 1-4 hours after surgery and continue thereafter with 150 mg each 24 hours for 10 days.
010.000.5552.00 010.000.5552.01	CAPSULE Each capsule contains: Dabigatran etexilate mesylate equivalent to 110 mg. dabigatran etexilate Container with 30 capsules. Container with 60 capsules.		Oral. Adults: Hip surgery, 110 mg, 1-4 hours after surgery and continue thereafter with 220 mg each 24 hours for 28 to 35 days. Knee surgery, 110 mg, 1-4 hours after surgery and continue thereafter with 220 mg each 24 hours for 10 days.

Generalities

It is a direct, competitive and reversible inhibitor of thrombin, an enzyme that catalyzes the transformation of fibrinogen into fibrin in the coagulation cascade, preventing the formation of thrombi. Dabigatran inhibits free thrombin, fibrin-bound thrombin, and thrombin-induced platelet aggregation.

Risk in pregnancy C

Adverse effects

Anemia, hematoma, wound bleeding, decreased hemoglobin, wound secretion, hematuria, hemarthrosis, thrombocytopenia, epistaxis, gastrointestinal bleeding, hemorrhoidal hemorrhage, ecchymosis, hemorrhage at catheter placement site, postoperative bleeding, wound bleeding, increase in ALT, increase in AST, increase in liver enzymes, increase in transaminases, nausea, vomiting, constipation.

Contraindications and precautions Contraindications:

Hypersensitivity to the drug, patients with severe renal failure. Precautions: Insufficiency liver, hemorrhagic risk, spinal/epidural anesthesia/lumbar puncture.

Interactions

Anticoagulants and antiplatelet medications, non-steroidal anti-inflammatory drugs (NSAIDs), potent P-glycoprotein inhibitors, P-glycoprotein inducers.

DARATUMUMAB

Clue	Description	Indications In	Route of administration and dosage
010.000.6207.00	INJECTABLE SOLUTION Each vial contains: Daratumumab 100.00 mg Container with vial with 100 mg in 5 mL (20 mg/mL).	combination with an immunomodulatory agent and dexamethasone for the treatment of patients with multiple myeloma who have received at least three lines of prior treatment.	Who have received prior treatment Intravenous Adults 16 mg/kg body weight administered as an intravenous infusion according to the following schedule:
010.000.6208.00	INJECTABLE SOLUTION Each vial contains: Daratumumab 400.00 mg Container with vial with 400 mg in 20 mL (20 mg/mL).	In combination bortezomib, with thalidomide and dexamethasone in patients with multiple myeloma who have not received prior treatment and who are candidates for autologous hematopoietic cell transplantation.	In combination with lenalidomide and dexamethasone: Dosing regimens with administration in 4-week cycles: Weeks 1 to 8: Weekly doses total) Weeks 9 to 24: Every two weeks (8 doses total) Week 25 onwards until disease progression: Every four weeks. Who have not received prior treatment Intravenous.

			The recommended dose of daratumumab in combination with bortezomib, thalidomide, and dexamethasone in cycles of 4 weeks to 16mg/kg administered as an intravenous infusion according to the dosing regimen. INDUCTION Weeks 1 to 8: weekly (total of 8 doses) Weeks 9 to 16: every 2 weeks (total of 4 doses) Stop for high-dose chemotherapy and TACHP CONSOLIDATION Week 1 to 8: every 2 weeks (4 doses total)

Generalities

Daratumumab is a human monoclonal immunoglobulin G1 kappa (IgG1ÿ) antibody against the CD38 antigen produced in mammalian cell lines (Chinese hamster ovary [CHO] using recombinant DNA technology.

Risk in Pregnancy

There are no data in humans or animals to evaluate the risk of using Daratumumab during pregnancy. IgG1 monoclonal antibodies are known to cross the placenta after the first trimester of pregnancy, so the drug should not be used during this period.

Women of reproductive potential should use effective contraception during and for 3 months after discontinuation of daratumumab treatment.

Daratumumab is contraindicated during pregnancy and lactation, when combined with other chemotherapeutic agents, review the prescribing information for these medications.

Adverse effects

The most common adverse events (>20%) were infusion reactions, diarrhea, constipation, nausea, peripheral edema, fatigue, back pain, asthenia, pyrexia, upper respiratory tract infection, bronchitis, pneumonia, decreased appetite, muscle spasms, peripheral sensory neuropathy, dyspnea and cough.

The administration of daratumumab presented a risk of infusion-related reactions (IRR) in around half of the patients, including anaphylactic reactions, most of the reactions occurred in the first infusion and were Grade 1-2.

Neutropenia and thrombocytopenia also occurred, as well as reactivation of hepatitis B virus infection.

Contraindications and Precautions

Contraindications: It is contraindicated in women who are or may become pregnant (see Restrictions on use during pregnancy and lactation). Precautions: Patients with latent Hepatitis B virus infection, dehydration.

Interactions

No drug interaction studies have been carried out.

Clinical pharmacokinetic evaluations of daratumumab in combination with thalidomide, bortezomib, and dexamethasone indicated no clinically relevant drug interactions between daratumumab and these small molecule medications.

DARBEPOETIN ALFA

Clue	Description	Indications	Route of administration and dosage
010.000.5632.00	INJECTABLE SOLUTION Each prefilled syringe contains: Darbepoetin alfa 300 µg. Package with 1 microsyringe with 0.6 mL.	Anemia in adult cancer patients with non-cancer neoplasms myeloids receive chemotherapy.	Subcutaneous. Adults: Initial dose: 500 µg once every 3 weeks, or a dose of 2.25 µg/kg body weight administered once a week. Once the therapeutic objective has been achieved, the dose should be reduced by 25 to 50% to ensure that the lowest dose is used to maintain the hemoglobin (Hb) level necessary to control the symptoms of anemia.
010.000.5633.00	INJECTABLE SOLUTION Each prefilled syringe contains: Darbepoetin alfa 500 µg. Package with 1 microsyringe with 1.0 mL.		

Generalities

Darbepoetin alfa stimulates erythropoiesis by the same mechanism as the endogenous hormone. Darbepoetin alfa has five N-linked sugar chains while the endogenous hormone and recombinant human erythropoietins (r-HuEPO) have three. The additional sugar residues are molecularly indistinguishable from those of the hormone

endogenous. Due to this higher carbohydrate content, darbepoetin alfa has a higher terminal half-life than r-HuEPO and, consequently, greater *in vivo activity.* Despite these molecular changes, darbepoetin alfa and r-HuEPO have identical mechanisms of action and darbepoetin alfa maintains the high specificity for the erythropoietin receptor demonstrated by r-HuEPO.

Risk in pregnancy c

Adverse effects

Headache, hypertension, skin rash, thromboembolic events, pain at the injection site.

Contraindications and precautions

Contraindications: Hypersensitivity to the drug.
Precautions: In order to ensure effective erythropoiesis, iron levels should be determined in all patients before and during treatment. Supplemental iron treatment is recommended in patients whose
Serum ferritin is less than 100 ÿg/l or whose transferrin saturation is less than 20%. Although rare, lack of response to treatment with Darbepoetin alfa should be investigated to determine its causes. Folic acid or vitamin B12 deficiencies reduce the effectiveness of erythropoiesis-stimulating factors and, therefore, must be corrected.
Likewise, severe aluminum poisoning, inter-recurrent infections, traumatic or inflammatory episodes,
Occult blood loss, hemolysis or marrow fibrosis can compromise the erythropoietic response. The
Blood pressure should be monitored in all patients with chronic renal failure, particularly during the initiation of treatment with Darbepoetin alfa. Patients should be advised of the importance of compliance with antihypertensive treatment and dietary restrictions. If blood pressure is difficult to control by implementing appropriate measures, hemoglobin can be reduced by reducing or stopping the dose of Darbepoetin alfa.
Darbepoetin alfa should be used with caution in patients with sickle cell anemia or epilepsy.

Interactions

The clinical results obtained so far do not indicate any interaction of Darbepoetin alfa with other substances.
However, there is a potential interaction with drugs that are highly erythrocyte-targeting, e.g., Cyclosporine, Tacrolimus. If darbepoetin alfa is administered concomitantly with any of these drugs, their blood levels should be monitored and their doses should be adjusted as hemoglobin increases.

DEFERASIROX ***(In Catalog II program)***

Clue	Description	Indications	Route of administration and dosage
010.000.2204.00	COMPRESSED Each tablet contains: Deferasirox 125 mg. Package with 28 tablets.	Transfusion of the hemosiderosis treatment.	Oral. Adults and children over 2 years of age: 10-30 mg/kg body weight. Maintenance dose: 5 to 10 mg/kg body weight. Monitor serum ferritin monthly and adjust dose every 3 or 6 months. Doses greater than 30 mg/kg body weight are not recommended. If serum ferritin is less than 500 µg/L interrupt treatment. The tablets are dispersed by stirring them in a glass of water or orange juice. The tablets should not be chewed or swallowed whole.
010.000.2206.00	COMPRESSED Each tablet contains: Deferasirox 500 mg. Package with 28 tablets.		

Generalities

Deferasirox is an orally active chelator with great selectivity for iron.

Risk in Pregnancy c

Adverse effects

Diarrhea, constipation, vomiting, nausea, abdominal pain and distension, dyspepsia, headache, rash, pruritus, increased transaminases, increased serum creatinine, proteinuria.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.

Precautions: Patients with renal or hepatic insufficiency, control of serum creatinine and transaminases, do not administer with other iron chelators, patients with galactose intolerance.

Interactions

With antacids containing aluminum, take deferasirox on an empty stomach, do not take with apple juice.

DESMOPRESSIN

Clue	Description	Indications von's	Route of administration and dosage
010.000.5169.00	INJECTABLE SOLUTION Each vial contains: Desmopressin acetate 15 µg. Container with 5 vials with 1 mL.	disease Willebrand type Ib.	Intravenous. Adults: 0.3 µg/kg body weight. It can be repeated after 6 hours.

Generalities

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

Risk in Pregnancy b

Adverse effects

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

Contraindications and Precautions

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

Interactions

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

DEXAMETHASONE

Clue	Description	Indications	Route of administration and dosage
010.000.4241.00	INJECTABLE SOLUTION Each vial or vial contains: Dexamethasone sodium phosphate equivalent to 8 mg. of dexamethasone phosphate. Container with a vial or vial with 2 mL.	Anemia and thrombocytopenia autoimmune. Leukemia. Lymphoma. Intravascular coagulation syndrome. Cerebral edema.	Intravenous, intramuscular. Adults: 4 to 20 mg/day, in higher doses divided every 6 to 8 hours. Maximum dose: 80 mg/day. Individualize dosage according to clinical response.

Generalities

Reduces inflammation, stabilizing the lysosomal membranes of leukocytes. It suppresses the immune response, stimulates the bone marrow and influences protein, lipid and carbohydrate metabolism.

Risk in Pregnancy c

Adverse effects

Hypertension, non-cerebral edema, cataracts, glaucoma, peptic ulcer, euphoria, insomnia, psychotic behavior, hypokalemia, hyperglycemia, acne, rash, delayed healing, atrophy at injection sites, muscle weakness, withdrawal syndrome.

Contraindications and Precautions

Contraindications: Hypersensitivity to corticosteroids, systemic infections, uncontrolled diabetes mellitus, glaucoma, gastritis.

Precautions: Systemic arterial hypertension.

Interactions

With phenobarbital, ephedrine and rifampin their elimination is accelerated, indomethacin and aspirin increase the risk of gastrointestinal bleeding.

ELTROMBOPAG

Clue	Description	Indications	Route of administration and dosage
010.000.5636.00	TABLET Each tablet contains: Eltrombopag olamine equivalent to 25 mg from eltrombopag. Package with 28 tablets.	Patient treatment of adults and pediatrics 6 years and older with chronic Idiopathic Thrombocytopenic Purpura (ITP) refractory to conventional to treatments	Oral. PTI: Adults and pediatrics from 6 to 17 years: 50mg every 24 hours Dosing regimens with Eltrombopag should be individualized based on the patient's platelet count (dose range: 25 mg-75 mg). Use the lowest effective dosing regimen to maintain platelet counts, as clinically indicated. In most patients, measurable increases in platelet count take 1-2 weeks.
010.000.5637.00	TABLET Each tablet contains: Eltrombopag olamine equivalent to 50 mg from eltrombopag. Package with 28 tablets.	therapies and rescue and in non-splenectomized patients who have contraindications for surgery. Treatment of cytopenias in patients with severe aplastic anemia (SAA) who have had an insufficient response to immunosuppression therapy.	Severe Aplastic Anemia: The initial dose of eltrombopag should be started with 50 mg once a day. Dosage adjustment: Platelet count < 50,000 µl after at least two weeks of treatment: increase the dose by 50 mg to a maximum of 150 mg/day. Platelet count > 200,000 µl < 400,000 µl at any time: Decrease the daily dose by 50 mg. Wait two weeks to evaluate the effect of this dose adjustment and each subsequent adjustment. Platelet count > 400,000 µl: Temporarily discontinue eltrombopag administration for at least one week. Once the platelet count is < 150,000 µl, resume treatment with a 50mg dose minor. Platelet count > 400,000 µl after two weeks of treatment with the lowest dose of eltrombopag: Permanently discontinue treatment with eltrombopag.

Generalities

Non-peptide thrombopoietin receptor agonist to increase platelet count and reduce or prevent bleeding.

Risk in Pregnancy

C

Adverse effects

Pharyngitis, urinary infections, nausea, vomiting, diarrhea, dry mouth, alopecia, rash, pruritus, skeletal muscle pain, myalgia, arthralgia, fatigue, dry eye, cataract, increased concentrations of aspartate amino transferase and alanine amino transferase.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug during pregnancy and breastfeeding, in children under 18 years of age and severe liver failure.
Precautions: Liver monitoring and ophthalmologist monitoring is recommended. In case of hemorrhage, stop administering the medication and go to your treating doctor immediately.

Interactions

HMG CoA Reductase inhibitors (pravastatin, sinvastatin, lovastatin and rosuvastatin).
Substrate of OATP1B1 and BCRP (Methotrexate/Topotecan).
Cytochrome P450 substrate.

EMICIZUMAB

Clue	Description	Indications	Route of administration and dosage
010.000.6199.00	INJECTABLE SOLUTION Each vial contains: Emicizumab 30 mg. Box with vial with 1 mL	Routine prophylaxis in patients with Hemophilia A with factor VIII inhibitors, which are difficult to control. Routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in adults and children with hemophilia	Subcutaneous Children and adults: 3 mg/Kg once a week for the first 4 weeks. Followed by permanent maintenance through one of the following modalities: - 1.5 mg/kg once a week, or, - 3 mg/kg every two weeks, or,
	INJECTABLE SOLUTION Each vial contains:		

010.000.6200.00	Emicizumab 60 mg. Box with vial with 0.4 mL	A, (congenital factor VIII deficiency) severe without factor VIII inhibitors. Emicizumab can be used in all age groups.	- 6 mg/kg every 4 weeks.
010.000.6201.00	INJECTABLE SOLUTION Each vial contains: Emicizumab 105 mg. Box with vial with 0.7 mL		
010.000.6202.00	INJECTABLE SOLUTION Each vial contains: Emicizumab 150 mg. Box with vial with 1 mL		

Generalities

Emicizumab is a humanized monoclonal antibody modified to immunoglobulin G4 (IgG4), with a bispecific antibody structure. Emicizumab binds factor IX and factor X to mimic the function of activated factor VIII.

Risk in Pregnancy c

Adverse effects

Reactions at the injection site, headache, arthralgia.
The most serious adverse reactions are thrombotic microangiopathy (TMA) and thrombotic events.

Contraindications and Precautions

Contraindicated in patients with known hypersensitivity to emicizumab or any of its excipients.
Treatment with bridging agents should be discontinued the day before starting emicizumab therapy.
Clinicians should discuss with all patients or caregivers the exact dosage and schedule of bridging agents to use if necessary while receiving emicizumab prophylaxis.
Emicizumab increases the patient's clotting potential. Therefore, the required dose of bridging agents may be lower than that used without emicizumab prophylaxis. The dose and duration of treatment with bridging agents
It will depend on the location and magnitude of the bleeding, as well as the patient's clinical condition. Avoid using the activated prothrombin complex concentrate (aPCC) unless no other treatment options or alternatives are available. If aPCC is indicated in a patient receiving emicizumab prophylaxis, the initial dose should not exceed 50 U/kg and monitoring is recommended if bleeding is not controlled with the initial dose of aPCC until
50 U/kg, additional doses of aPCC should be administered under medical direction or supervision and the total dose of aPCC It should not exceed 100 U/kg in the first 24 hours of treatment.

Interactions

There have not been sufficient or well-controlled drug interaction studies with emicizumab.
Clinical experience suggests that there is a drug interaction with emicizumab and activated prothrombin complex concentrate (aPCC).
There is a possibility of hypercoagulability with rFVIIa or FVIII with emicizumab based on preclinical experiments, although the clinical significance of these data is unknown.

ENOXAPARIN

Clue	Description	Indications	Route of administration and dosage
010.000.4242.00 010.000.4242.01	INJECTABLE SOLUTION Each syringe contains: Enoxaparin sodium 20 mg. Package with 2 0.2 mL syringes. Package with 2 syringes with 0.2 mL safety device	Anticoagulant. Coagulation prophylaxis in thromboembolic disease. Coagulation prophylaxis in the extracorporeal circulation circuit.	Deep subcutaneous, intravascular (arterial line of the circuit). Adults: 1.5 mg/kg body weight in a single injection or 1.0 mg/kg body weight in two daily injections. 20-40 mg before starting surgery and for 7 to 10 days after.
010.000.2154.00 010.000.2154.01	INJECTABLE SOLUTION Each syringe contains: Enoxaparin sodium 40 mg. Package with 2 0.4 mL syringes. Package with 2 syringes with 0.4 mL safety device.		

	INJECTABLE SOLUTION Each syringe contains Enoxaparin sodium 60 mg. Package with 2 0.6 mL syringes. Package with 2 syringes with 0.6 mL safety device Container with 1 Syringes. of 0.6 mL Container with 10 Syringes. of 0.6 mL Container with 30 Syringes. 0.6 mL		
010.000.4224.00 010.000.4224.01 010.000.4224.02 010.000.4224.03 010.000.4224.04			

Generalities

Low molecular weight heparin made up of a mixture of mucopolysaccharides in short homogeneous chains. Antithrombotic action with lower risk of causing bleeding.

Risk in Pregnancy d

Adverse effects

Hemorrhage due to thrombocytopenia. Ecchymosis at the injection site.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Acute bacterial endocarditis, severe blood coagulation diseases, active gastro-duodenal ulcer, stroke, thrombocytopenia with positive platelet aggregation *in vitro,* hypersensitivity.

Interactions

Nonsteroidal anti-inflammatories and dextrans increase the anticoagulant effect, while protamine antagonizes it.

ENOXAPARIN SODIUM

Clue	Description	Indications	Route of administration and dosage
010.000.5931.00	INJECTABLE SOLUTION Each syringe contains: Enoxaparin sodium 80 mg. Container with 2 syringes with safety device 0.8 mL.	Anticoagulant. Coagulation disease prophylaxis in the thromboembolic. Coagulation prophylaxis in the extracorporeal circulation circuit.	Deep subcutaneous, intravascular (arterial line of the circuit). Adults: 1.5 mg/kg body weight in one injection or 1.0 mg/kg body weight in two daily injections. 20-40 mg before starting surgery and for 7 to 10 days later.

Generalities

Low molecular weight heparin made up of a mixture of mucopolysaccharides in short homogeneous chains. Antithrombotic action with lower risk of causing bleeding.

Risk in Pregnancy c

Adverse effects

Hemorrhage due to thrombocytopenia. Ecchymosis at the injection site.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.
Precautions: Acute bacterial endocarditis, severe blood coagulation diseases, active gastro-diuodenal ulcer, stroke, thrombocytopenia with positive platelet aggregation in vitro

Interactions

Nonsteroidal anti-inflammatories and dextrans increase the anticoagulant effect, while protamine antagonizes it.

EPTACOG ALFA (RECOMBINANT ALFA COAGULATION FACTOR VII

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION Each vial with lyophilisate contains:	Bleeding episodes and prevention of excessive bleeding related to surgery in patients with hereditary hemophilia or	Intravenous. Adults: 90 µg/kg body weight first dose.

	Recombinant coagulation factor VII alpha 60,000 IU (1.2 mg) or 1 mg (50 KUI)	acquired have developed inhibitors coagulation factors VIII and IX.	For severe bleeding, apply subsequent doses of 90 µg/kg of body weight every 3 to 6 hours. Children: 90 to 120 µg/kg body weight first dose. Subsequently 90 to 120 µg/kg body weight every 3 to 6 hours.
010.000.4238.00	Package with a vial with lyophilisate (1.2 mg) and a vial with 2 mL of diluent, and equipment for administration.		
010.000.4238.01	Package with a vial with lyophilisate (1 mg) and a vial with 1.0 mL or 1.1 mL of diluent.		
010.000.4238.02	Package with a vial with lyophilisate (1 mg) and a prefilled syringe with 1.0 mL of diluent and a vial adapter.		
	INJECTABLE SOLUTION Each vial with lyophilisate contains: Recombinant coagulation factor VII alpha 120,000 IU (2.4 mg) or 2 mg (100 KUI)		
010.000.4245.00	Package with a vial with lyophilisate (2.4 mg) and a vial with 4 mL of diluent, and equipment for administration.		
010.000.4245.01	Package with a vial with lyophilisate (2 mg) and a vial with 2.0 mL or 2.1 mL of diluent.		
010.000.4245.02	Package with a vial with lyophilisate (2 mg) and a prefilled syringe with 2.0 mL of diluent and a vial adapter.		
	INJECTABLE SOLUTION Each vial with lyophilisate contains: Recombinant coagulation factor VII alpha 240,000 IU (4.8 mg) or 5 mg (250 KUI)		
010.000.4250.00	Package with a vial with lyophilisate (4.8 mg) and a vial with 8 mL of diluent, and equipment for administration.		
010.000.4250.01	Package with a vial with lyophilisate (5 mg) and a vial with 5.0 mL or 5.2 mL of diluent.		
010.000.4250.02	Package with a vial with lyophilisate (5 mg) and a prefilled syringe with 5.0 mL of diluent and a vial adapter.		

Generalities

Structurally very similar to activated factor VII derived from human plasma. Designed for the treatment of hemophiliac patients who have developed inhibitors to coagulation factors VIII (FVIII) and IX (FIX) and is obtained through recombinant technology through cloning and expression of genes in freshly hamster kidney cells.
born.

Risk in Pregnancy

c

Adverse effects

Pain, fever, headache, nausea and vomiting, changes in blood pressure and skin rash. Thrombotic events and coagulation disorders such as plateletopenia, decreased fibrinogen and the presence of D-dimer have been reported.

Contraindications and Precautions

Contraindications: Hypersensitivity to bovine hamster or mouse proteins.
Precautions: Advanced atherosclerosis, polytrauma and sepsis in which tissue factor could be overexpressed with potential risk of developing thrombotic events or inducing disseminated intravascular coagulation (DIC); mild or moderate bleeding. The duration of outpatient treatment should not exceed 24 hours. If the bleeding episode does not subside, the patient should be immediately referred to the hospital.

Interactions

None of clinical importance.

HUMAN ANTIHEMOPHILIC FACTOR

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION Each vial with lyophilisate contains: Antihemophilic factor human 250 IU. Package with a vial, vial with diluent and administration equipment.	Treatment or prevention of bleeding in patients with Hemophilia A (factor VIII deficiency).	Slow IV. Adults and children: 10 to 20 IU/kg, followed by 10 to 25 IU/kg every 8-12 hours, until bleeding is controlled.
010.000.4239.00			

Generalities

Antihemophilic factor (Factor VIII) is a high molecular weight glycoprotein that functions as a cofactor in the coagulation cascade.

Risk in Pregnancy

c

Adverse effects

Pain at the injection site, headache, vertigo, allergic reactions.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, the administration of high doses can cause hemolysis in patients with blood group A, B, or AB, do not use a glass syringe for administration.

Interactions

None of clinical importance.

ANTIHEMOPHILICA FACTOR VIII, VON WILLEBRAND FACTOR

Clue	Description	Indications Von	Route of administration and dosage
	INJECTABLE SOLUTION Each vial with lyophilisate contains: Antihemophilic factor VIII Human 500 IU Factor Von Willebrand 500 IU Protein 7.5 mg Container with a vial with lyophilisate and a vial with 5 mL of diluent.	Willebrand disease with acute bleeding without response to desmopressin.	Intravenous. Adults and children over 6 years of age: Von Willebrand disease: The ratio between FVIII:C and VWF:CoR is approximately 1:1, usually 1 IU/kg of weight FVIII:C and VWF:CoR increase their plasma level from 1.5 to 2% of normal activity for the respective protein. Usually 20 to 50 IU/kg body weight are necessary to achieve primary hemostasis. A dose of 50 to 80 IU/kg body weight required, especially in patients with VWD type 3, where adequate maintenance of plasma levels could require higher doses than other types of VWD.
010.000.6058.00			
	INJECTABLE SOLUTION Each vial with lyophilisate contains: Antihemophilic factor VIII Human 1,000 IU Von Willebrand factor 1 000 IU Protein 15 mg		
010.000.6059.00			

	Container with a vial with lyophilisate and a vial with 10 mL of diluent.		

Generalities

Von Willebrand Factor is a large multimeric protein, with three key functions: VWF is the mediator of platelet adhesion and aggregation processes at sites of vascular damage, critical processes for both hemostasis and thrombosis; It is also a protein that protects Factor VIII from its inactivation and rapid catabolism, by formation of the FVIII – VWF complex through non-covalent bonding.

Risk in Pregnancy c

Adverse effects

Urticaria, vertigo, dyspnea, nausea, vomiting and cough. Allergic reactions such as angioedema, burning and itching sensations at the injection site, chills, flushing, headache, hives, hypotension, lethargy, restlessness, tachycardia, chest tightness, itching sensation, have been observed very rarely and may in some cases progress to severe anaphylaxis (including shock).

Contraindications and Precautions

Contraindications: Hypersensitivity to the components of the biological.
Precautions: Thromboembolic events associated with human blood coagulation Factor VIII/Von Willebrand Factor. Potential to induce antibodies to Factor VIII and antibodies to Von Willebrand Factor, especially in type 3. Theoretical risk of transmission of infectious agents since the product is made from human plasma.

Interactions

None known with other medicinal products.

FACTOR VIII OF HUMAN BLOOD COAGULATION/ VON'S FACTOR WILLEBRAND

Clue	Description	Indications	Route of administration and dosage
010.000.5643.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Human blood coagulation factor VIII 250 IU. Von Willebrand factor 600 IU. Container with a vial with lyophilisate and a vial with 5 mL of diluent.	Event handling of bleeding in patients with Von Willebrand disease, and who are not candidates to be treated with desmopressin. Management of acquired factor VIII deficiency and treatment of patients with antibodies against factor VIII (Induction of Immune Tolerance).	Intravenous Adults and children: Dose of 40-80 IU/Kg of body weight of von Willebrand Factor. Evaluate a dose adjustment after 12-24 hours depending on the severity of bleeding. An initial dose of 80 IU/Kg of body weight may be required, especially in vW disease type 3 where maintenance of adequate levels may require higher doses than in other types of this disease. The dose and duration of treatment depend on the clinical picture, severity of bleeding, and vW factor levels.
010.000.5644.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Human blood coagulation factor VIII 500 IU. Von Willebrand factor 1200 IU. Container with a vial with lyophilisate and a vial with 10 mL of diluent.		

Generalities

Von Willebrand factor in stable, purified, sterile, lyophilized plasma concentrate that behaves like endogenous VWF and has protective properties of coagulation factor VIII. vW factor mainly participates in platelet adhesion and aggregation at sites of vascular damage.

Risk in Pregnancy c

No clinical studies have been conducted to evaluate the safety of use during pregnancy and lactation.

Adverse effects

Nausea, abdominal discomfort, dizziness and fever. In patients with VWD, especially type 3, neutralizing (inhibitory) antibodies to VWF may very rarely develop. If these inhibitors occur, they will manifest as an inadequate clinical response. Thromboembolic events associated with high plasma levels of FVIII in

patients who are repeatedly treated with plasma concentrates; especially in patients with added risk factors such as major surgery, age, obesity, immobilization.

Contraindications and Precautions

Contraindications: Hypersensitivity to the biological.
Precautions: Monitoring of plasma FVIII:C levels is recommended in order to avoid excessive and sustained plasma levels that may increase the risk of thrombotic events.

Interactions

None of clinical importance.

FACTOR VIII OF HUMAN COAGULATION

Clue	Description	Indications	Route of administration and dosage
010.000.4324.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Human coagulation factor VIII 500 IU. Container with a vial with lyophilisate, a vial with 5 mL or 10 mL of diluent and administration equipment.	Treatment or prevention of bleeding in patients with hemophilia A (factor VIII deficiency)	Intravenous. The dosage and duration of therapy is based on the amount of factor deficiency, severity and location of bleeding, and the clinical course of the disease.

Generalities

Antihemophilic factor (Factor VIII) is a high molecular weight glycoprotein that functions as a cofactor in the coagulation cascade.

Risk in Pregnancy C

Adverse effects

Pain at the injection site, headache, vertigo, allergic reactions.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.
Precautions: The administration of high doses can cause hemolysis in patients with blood group A, B, or AB, do not use a glass syringe for administration.

Interactions

None of clinical importance.

RECOMBINANT FACTOR VIII

Clue	Description	Indications	Route of administration and dosage
010.000.5252.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Recombinant Factor VIII 250 IU. Package with a vial with lyophilisate, a vial with 10 mL of diluent or syringe with 2.5 mL of diluent and administration equipment.	Treatment or prevention of bleeding in patients with hemophilia A (factor VIII deficiency).	Slow IV Adults and children: Treatment: 10 to 20 IU/Kg of body weight, every 8-12 hours, until bleeding is controlled. Prevention: Followed by 10 to 25 IU/Kg of body weight, two or three times a week.
010.000.5253.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Recombinant Factor VIII 500 IU. Package with a vial with lyophilisate, a vial with 10 mL of diluent or syringe with 2.5 mL of diluent and administration equipment.		

Generalities

Antihemophilic factor (factor VIII) is a highly purified glycoprotein manufactured with recombinant DNA technology in hamster cells into which the human factor VIII gene was introduced. which functions as a cofactor in the coagulation cascade.

Risk in Pregnancy

c

Adverse effects

Local reaction at the site of administration, dizziness, rash, taste alterations, mild hypertension, dyspnea, pruritus, disorientation, nausea and rhinitis. Rarely serious allergic reactions such as anaphylaxis in young people.

Contraindications and Precautions

Contraindications: Known intolerance to the components of the formula. Hypersensitivity to mouse or hamster proteins.

Precautions: Administer only after demonstrating factor VIII deficiency. Clinically and laboratoryly monitor the development of anti-factor VIII antibodies (Inhibitors).

Interactions

None known so far.

FACTOR IX OR NONACOG ALFA

Clue	Description	Indications	Route of administration and dosage
010.000.5238.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Factor IX 400 to 600 IU. Container with a vial and diluent.	Factor IX deficiency (Hemophilia b – Christmas of Disease). Anticoagulant with poisoning.	Slow IV. Adults and children: The units required are calculated by multiplying 0.8 to 1/ body weight in kg/% of desired increase in factor IX concentration in infusion or slow injection. Individualized dose according to degree of efficiency, factor IX value, patient weight and severity of bleeding.
010.000.5343.00 010.000.5343.01	INJECTABLE SOLUTION Each vial with lyophilisate contains: Recombinant coagulation factor or nonacog alfa 500 IU. Container with vial bottle with lyophilisate and vial bottle with diluent. Container with a vial with lyophilisate, a syringe with 5 mL of diluent, an infusion set, an adapter.	Treatment of hemophilia B deficiency (Christmas disease). Prophylaxis of bleeding due to factor IX deficiency.	Slow IV. Adults: Body weight in kg multiplied by the desired percentage increase in factor IX multiplied by 1.2 IU. Children under 15 years old: Body weight in kg multiplied by the desired percentage increase in factor IX multiplied by 1.4 IU.
010.000.5344.00 010.000.5344.01	INJECTABLE SOLUTION Each vial with lyophilisate contains: Recombinant coagulation factor or nonacog alfa 1000 UI. Container with vial bottle with lyophilisate and vial bottle with diluent. Container with a vial with lyophilisate, a syringe with 5 mL of diluent, an infusion set, an adapter.		

Generalities

Directly restores the deficient coagulation factor.

Risk in Pregnancy

c

Adverse effects

Thromboembolism, intravascular hemolysis in patients with blood type A, B or AB, fever, flushing, tingling, hypersensitivity, headache.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Hepatopathy, intravascular coagulation, fibrinolysis.

Interactions

None of clinical importance.

HUMAN FIBRINOGEN

Clue	Description	Indications	Route of administration and dosage
010.000.6070.00	INJECTABLE SOLUTION Each vial with lyophilized powder contains: Human fibrinogen 1.50 g Container with a vial with lyophilisate and a vial with 100 mL of diluent	Complementary therapy in the management of severe uncontrolled bleeding due to low fibrinogen levels, in life-threatening bleeding during obstetric complications. Complementary therapy in the management of severe uncontrolled bleeding due to low fibrinogen levels, in life-threatening bleeding during complications caused by trauma.	Intravenous. Adults: In general, an initial dose of 1 to 2 g. In case of acute severe obstetric hemorrhage, a larger amount of fibrinogen (4 to 8 g) may be required. Children: The dosage should be established based on body weight and clinical context (0.02 to 0.03 g/kg).

by

Generalities

Fibrinogen is transformed into fibrin by the action of thrombin and in the presence of activated factor XIII and calcium ions, forming a stable three-dimensional fibrin network that ensures coagulation.

Risk in Pregnancy

x

Adverse effects

Headache, night sweats, chills, hypertemia, thrombosis and transient arterial hypotension.

Contraindications and Precautions

Contraindications: Hypersensitivity to the biological.
Precautions: For the treatment of severe acute bleeding, human fibrinogen should be prescribed in association with appropriate intensive care measures depending on your clinical and biological status. There is a risk of thrombosis in patients treated with human fibrinogen for congenital or acquired deficiencies, mainly in case of high doses and repeated doses. Patients treated with human fibrinogen should be closely monitored.
to detect any signs or symptoms of thrombosis. The potential benefit of treatment with human fibrinogen must be weighed against the thromboembolic risks in the following situations: in patients with a history of coronary heart disease or myocardial infarction, with liver failure, during or after surgery, in newborns or in patients with risk of thromboembolic complications or disseminated intravascular coagulation. Close monitoring is necessary.

Interactions

There is no known interaction with other medications.

HEPARIN

Clue	Description	Indications	Route of administration and dosage
010.000.0621.00	INJECTABLE SOLUTION Each vial contains: Heparin sodium equivalent to 000 IU 10 of heparin. Package with 50 vials with 10 mL (1000 IU/mL).	Anticoagulant for in-hospital use Disseminated intravascular coagulation. Prevention and treatment of pulmonary thromboembolism,	Intravenous. Adults: Initial 5,000 IU. Subsequent: 5,000 to 10,000 IU every 6 hours up to a total of 20,000 IU daily and according to clinical response.
	INJECTABLE SOLUTION		

010.000.0622.00	Each vial contains: Heparin sodium equivalent to 25 000 IU of heparin. Package with 50 vials with 5 mL (5,000 IU/ mL).	Myocardial infarction. Hemodialysis. Extracorporeal circulation.	Children: Initial: 100 to 200 IU/kg/dose (equivalent of 1 to 2 mg/Kg/dose). Subsequent: Similar doses every 4 to 6 hours depending on the patient's clinical conditions and the anticoagulant effect obtained.
010.000.6267.00	INJECTABLE SOLUTION Each vial contains: Heparin sodium equivalent to 5000 IU Package with 50 vials with 5 mL.		

Generalities

Accelerates the formation of an antithrombin III and thrombin complex. It inactivates thrombin and prevents the conversion of fibrinogen to fibrin.

Risk in Pregnancy C

Adverse effects

Fever, anaphylactic reactions, alopecia, osteoporosis, thrombocytopenia, dermatitis, diarrhea, hypoprothrombinemia.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Hemorrhage, pregnancy, active peptic ulcer, severe liver failure, chronic alcoholism, severe high blood pressure, ingestion of salicylates.

Interactions

Oral anticoagulants produce synergistic action. With salicylates the anticoagulant effect increases, do not use them associates.

HYDROXOCOBALAMINE

Clue	Description	Indications	Route of administration and dosage
010.000.1708.00	INJECTABLE SOLUTION Each vial or vial with solution or lyophilisate contains: Hydroxocobalamin 100 µg. Container with 3 2 mL vials or vial and diluent.	Megaloblastic anemias due to vitamin deficiency B12.	Intramuscular. Adults and children: Initial: 50 to 100 µg/day or every other day, for two to four weeks Maintenance: 100 to 200 µg every month.

Generalities

Coenzyme for various metabolic functions. Essential for cell replication and hematopoiesis.

Risk in Pregnancy TO

Adverse effects

Hypersensitivity reactions, chronic urticaria, diarrhea, pruritus, peripheral vascular thrombosis.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. It is not indicated in the treatment of peripheral neuritis or other pathological processes.

Interactions

With neomycin, colchicine, paraminosalicylic acid and chloramphenicol, malabsorption occurs. It should not be used in combination with these medications.

DEXTRAN IRON

Clue	Description	Indications	Route of administration and dosage
	INJECTABLE SOLUTION	Patients with iron deficiency anemia	Deep intramuscular or slow intravenous.

010.000.1705.00	Each vial contains: Iron in the form of iron dextran 100 mg. Container with 3 vials of 2 mL.	for whom the use of the oral route is contraindicated.	Adults and children over 50 kg in weight: 100 to 200 mg every 24 to 48 hours. Maximum intravenous dose: 100 mg. Children: Less than 5 kg: 25 mg/day. Of 5 to 9 kg: 50 mg/day. Over 50 kg: 100 mg/day.

Generalities

Provides iron, a basic component for the essential synthesis of hemoglobin.

Risk in Pregnancy c

Adverse effects

Arthralgia, anaphylactic shock, gluteal abscess, vascular collapse, enterorrhagia, phlebitis, arterial hypotension. It should not be used repeatedly or for a long time; headache, paresthesia, arthralgia, myalgia, dizziness, syncope, nausea, vomiting.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Headache, fever, chest pain, local pain, adenopathy, anemias other than iron deficiency.
Precautions: Do not use in liver dysfunction and rheumatoid arthritis.

Interactions

None of clinical importance.

IDARUCIZUMAB

Clue	Description	Indications	Route of administration and dosage
010.000.6133.00	INJECTABLE SOLUTION Each vial contains: Idarucizumab 2.5 g Package with 2 vials with 50 mL each (2.5 g/50 mL).	It is indicated as specific reversal agent for dabigatran and when rapid reversal of the anticoagulant effects of dabigatran is required: For emergency surgery/urgent procedures. In life-threatening or uncontrolled bleeding.	Intravenous. 5 g in two consecutive infusions (each 2.5 g) over 5 to 10 minutes each, or as a bolus injection. Administration of a second dose of 5 g should be considered in the following situations: Recurrence of clinically relevant bleeding associated with prolonged clotting times. The need for a second surgery or urgent procedure in patients who also have prolonged clotting times. Dabigatran treatment may be resumed 24 hours after idarucizumab administration, if the patient is clinically stable and adequate hemostasis has been achieved.

Generalities

Idarucizumab is a specific reversal agent for dabigatran. It is a monoclonal antibody fragment (Fab) that binds to dabigatran with very high affinity. Idarucizumab binds potently and specifically to dabigatran and its metabolites, neutralizing their anticoagulant effect.

Risk in Pregnancy c

Adverse effects

No adverse reactions have been identified.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.
Precautions: Adverse reactions due to hereditary fructose intolerance, appearance of anti-idarucizumab antibodies before and after treatment.

Interactions

None of clinical importance.

INTERFERON

Clue	Description	Indications	Route of administration and dosage
010.000.5245.00	INJECTABLE SOLUTION Each vial or syringe contains: Interferon alfa 2a 4.5 or 9 million IU. Package with a vial or syringe with a needle. – Each vial contains: Interferon alfa 2b 5, 18 or 25 million IU. Package with a vial with or without a vial with diluent.	Multiple myeloma. Malignant melanoma. cell leukemia hairy Kaposi sarcoma. Advanced renal carcinoma. Chronic granulocytic leukemia. Condyloma acuminata. Assistant in the treatment of chronic hepatitis B and C.	Subcutaneous or intramuscular. Adults and children: Dosage according to the specialist's opinion.
010.000.5245.01			

Generalities

Powerful cytokines with antiviral, antiproliferative and immunomodulatory effects.

Risk in Pregnancy C

Adverse effects

Fever, fatigue, arthralgias and headache, dizziness, sedation, confusion and depression, leukopenia and thrombocytopenia.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Heart, liver, kidney or thyroid failure.

Interactions

Increases the effects of depressants and decreases their elimination with aminophylline.

MOROCTOCOG ALPHA

Clue	Description	Indications	Route of administration and dosage
010.000.5760.00	INJECTABLE SOLUTION Each vial contains: Moroctocog alfa 250 IU. Package with a vial and a syringe prefilled with 4 mL of diluent.	Treatment of hemophilia A (blood coagulation modifier).	Intravenous infusion. Adults and children: The units required are calculated by multiplying body weight in Kg multiplied by the desired increase in factor VIII (% of normal or IU/dl) multiplied by 0.5 (IU/kg times IU/dl). The dosage and duration of treatment depend on the severity of factor VIII deficiency, the location and magnitude of bleeding, and the patient's clinical condition.
010.000.5761.00	INJECTABLE SOLUTION Each vial contains: Moroctocog alfa 500 IU. Package with a vial and a syringe prefilled with 4 mL of diluent.		
010.000.6014.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Moroctocog alfa 1000 IU. Package with a vial with lyophilisate, a prefilled syringe with 4 mL of diluent, an adapter and an infusion set.	Control and prevention of bleeding episodes and for routine and surgical prophylaxis in patients with hemophilia A (congenital Factor VIII deficiency or classic hemophilia). Moroctocog Alfa does not contain Von Willebrand factor and therefore NO	Intravenous infusion. Adults and children: The units required are calculated by multiplying body weight in kg multiplied by the desired increase in factor VIII (% normal or IU/dl) multiplied by 0.5 (IU/kg times IU/dl). The dosage and duration of treatment depend on the severity of the deficiency.

010.000.6015.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Moroctocog alfa 2000 IU. Package with a vial with lyophilisate, a prefilled syringe with 4 mL of diluent, an adapter and an infusion set.	It is indicated for Von Willebrand Disease.	of factor VIII, the location and magnitude of bleeding, and the patient's clinical condition.

Generalities

Moroctocog alfa contains recombinant B domain-deleted coagulation factor VIII (moroctocog alfa). It is a glycoprotein with an approximate molecular weight of 170,000 Dalton, consisting of 1438 amino acids. Moroctocog alfa has functional characteristics comparable to those of endogenous factor VIII. The activity of factor VIII is greatly reduced in patients with hemophilia A, and replacement therapy is therefore necessary.

Risk in Pregnancy

C

Adverse effects

Factor VIII Inhibitors – PUPs, Factor VIII Inhibitors – PTPs, Headache, Hemorrhage/hematoma, Vomiting, Nausea, Arthralgia, Asthenia, pyrexia, complicated vascular access including complications in the indwelling venous access catheter. Increased anti-CHO antibodies in laboratory tests, increased FVIII antibodies in laboratory tests.

Contraindications and Precautions

Contraindications: Hypersensitivity to the biological. Known allergic reaction to hamster protein.
Precautions: In patients receiving products containing coagulation factor VIII, antibodies neutralizing its activity (inhibitors) may develop. As with all products containing coagulation factor VIII, patients should be monitored for the development of inhibitors which should be titrated into Bethesda Units (BU) using appropriate biological assays. If expected plasma levels of factor VIII activity are not achieved or bleeding is not controlled with an adequate dose, evaluation should be done to determine the presence of a factor VIII inhibitor.

Interactions

There are no known interactions of recombinant coagulation factor VIII products with other medications.

OCTOCOG ALFA (FACTOR VIII OF HUMAN BLOOD COAGULATION RECOMBINANT rDNA)

Clue	Description	Indications	Route of administration and dosage
010.000.5850.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Octocog alfa 250 IU. Package with a vial with lyophilisate, a vial with 5 mL of diluent and a reconstitution kit.	Treatment and prophylaxis of bleeding in patients with hemophilia A. This medication does not contain von Willebrand factor and is therefore not indicated in von Willebrand disease.	Intravenous. Treatment. Adults and pediatrics. The dosage and duration of therapy are based on the amount of the deficiency factor, severity, location of the hemorrhage, and the clinical course of the disease.
010.000.5851.00	INJECTABLE SOLUTION Each vial with lyophilisate contains: Octocog alfa 500 IU. Package with a vial with lyophilisate, a vial with 5 mL of diluent and a reconstitution kit.		Prophylaxis Adults and pediatrics. For long-term prophylaxis against bleeding in patients with severe hemophilia A, the dose is 20 to 40 IU per kg of body weight at intervals of 2 to 3 days. In patients under 6 years of age, doses of 20 to 50 IU per kg of body weight, 3 to 4 times a week.

Generalities

Recombinant coagulation factor VIII is a glycoprotein that has an amino acid sequence comparable to human factor VIII and post-translational modifications that are similar to those present in plasma-derived molecules.

Risk in Pregnancy

Adverse effects

Hypersensitivity and anaphylaxis reactions, fever, rash, redness, face edema, urticaria, dyspnea and pruritus.
Inhibition of Factor VIII. Abdominal pain, diarrhea, headache, hyperhidrosis, dizziness, paresthesias.

Contraindications and Precautions

Contraindications: Known hypersensitivity to the active substance, to the excipients or to mouse or hamster proteins.
Hypersensitivity reactions and anaphylaxis, development of neutralizing antibodies (inhibitors) against Factor VIII have been documented.

Interactions

None known so far.

PRASUGREL

Clue	Description	Indications	Route of administration and dosage
010.000.5602.01	TABLET Each tablet contains: Prasugrel hydrochloride equivalent to 5 mg. of prasugrel Package with 28 tablets.	Antiplatelet agent to be used in patients with acute coronary syndrome undergoing scheduled percutaneous coronary intervention.	Oral. Adults With a weight greater than 60 kg and under 75 years of age: start treatment with a single loading dose of 60 mg and subsequently continue with a maintenance dose of 10 mg every 24 hours.
010.000.5603.01	TABLET Each tablet contains: Prasugrel hydrochloride equivalent to 10 mg. of prasugrel. Package with 28 tablets.		With a weight of less than 60 kg and greater than or equal to 75 years of age: start treatment with a single loading dose of 60 mg and subsequently continue with a maintenance dose of 5 mg every 24 hours. In turn, take acetylsalicylic acid from 75 mg to 325 mg, every 24 hours. Maintenance treatment for up to 12 months, unless discontinuation of treatment is clinically indicated.

Generalities

Prasugrel hydrochloride is an inhibitor of platelet aggregation and activation that acts through the specific and irreversible binding of its active metabolite to the platelet ADP receptor of the P2Y12 type and as a consequence inhibits numerous ADP-mediated platelet activities.

Risk in Pregnancy c

Adverse effects

Anemia, ocular hemorrhage, intracranial hemorrhage, epistaxis, hemoptysis, gastrointestinal hemorrhage, retroperitoneal hemorrhage, rectal hemorrhage, hematochezia, gingival hemorrhage, rash, ecchymosis, hematuria, vessel puncture site hematoma, puncture site hemorrhage, contusion, post-intervention hemorrhage.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, active pathological bleeding, history of cerebral vascular accident or transient cerebral ischemia and severe liver failure.
Precautions: Risk of bleeding. In the Triton-Timi clinical study 38, the main exclusion criteria included increased risk of bleeding, anemia, thrombocytopenia, and history of pathological intracranial findings. The
patients with acute coronary syndrome who were going to undergo percutaneous coronary intervention, treated with
Prasugrel hydrochloride and acetylsalicylic acid showed an increased risk of major and minor bleeding. Therefore, the use of prasugrel hydrochloride should only be considered in patients with an increased risk of bleeding when the benefits in terms of prevention of ischemic events are considered to be greater than the risk of serious bleeding.

Interactions

Warfarin. Concomitant administration of prasugrel with coumarin derivatives other than warfarin has not been studied. Due to the potential increased risk of bleeding, warfarin (or other coumarin derivatives) and prasugrel hydrochloride should be coadministered with caution.
Chronic concomitant administration of NSAIDs has not been studied. Due to the potential for increased bleeding risk, chronic NSAIDs (including COX-2 inhibitors) and prasugrel hydrochloride should be coadministered with caution.
with

RIVAROXABAN

Clue	Description	Indications	Route of administration and dosage
010.000.5544.00 010.000.5544.01	COMPRESSED Each tablet contains: Rivaroxaban 10 mg. Package with 10 tablets. Package with 30 tablets.	Prevention of venous thromboembolic events in adults undergoing elective total hip and knee replacement surgery.	Oral. Adults: Hip surgery, 10 mg every 24 hours for five weeks. Knee surgery, 10 mg every 24 hours for two weeks. The initial dose should be administered 6 to 10 hours after the end of the surgical intervention, provided that hemostasis has been restored.
010.000.5735.01	COMPRESSED Each tablet contains: Rivaroxaban 15 mg. Package with 28 tablets.	Pulmonary Embolism. recurrent EPs. Deep venous thrombosis. Recurrent of the prevention.	Oral. Adults. Pulmonary Embolism. recurrent EPs. Starting dose: 15 mg twice daily for 3 weeks. Maintenance dose and prevention of PE and recurrent DVT: 20 mg, once daily. Deep venous thrombosis. Prevention of recurrences. Starting dose: 15 mg twice daily for 3 weeks. Maintenance dose and prevention of PE and Recurrent DVT: 20 mg once daily.
010.000.5736.01	COMPRESSED Each tablet contains: Rivaroxaban 20 mg. Package with 28 tablets.	Prevention of cerebral vascular event (CVE) and systemic embolism in patients with non-valvular atrial fibrillation.	Prevention of cerebral vascular event (CVE) and systemic embolism in patients with non-valvular atrial fibrillation. 20 mg once a day. Moderate renal failure (DCr 30-49 mL/min): 15 mg once daily. Administer with food.
010.000.5737.00	COMPRESSED Each tablet contains: Rivaroxaban 2.5 mg. Package with 56 tablets.	Prevention of cardiovascular death, myocardial infarction and stent thrombosis in patients who have suffered acute coronary syndrome (ACS) (myocardial infarction with or without ST-segment elevation or unstable angina) in combination with acid acetylsalicylic acid alone, or with acetylsalicylic acid plus thieonopyridines clopidogrel or ticlopidine. as Prevention of cerebrovascular event, myocardial infarction and cardiovascular death, and for the prevention of acute lower extremity ischemia and mortality in patients with coronary artery disease (CAD) or peripheral arterial disease (PAD) combination with acetylsalicylic acid (ASA) . in	Oral Adults: 2.5 mg twice daily, in combination with a daily dose of acetylsalicylic acid (75 mg to 100 mg) alone, or with acetylsalicylic acid plus a standard dose of thieonopyridine (75 mg clopidogrel or a standard daily dose of ticlopidine). The duration of treatment is at least 24 months. Oral 2.5 mg twice daily, in combination with a daily dose of 100 mg of acetylsalicylic acid.

Generalities

Rivaroxaban is a highly selective direct factor Xa inhibitor with oral bioavailability.

Risk in Pregnancy

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Adverse effects

Anemia, thrombocythemia, nausea, dyspepsia, dry mouth, vomiting, localized edema, feeling unwell, fever, peripheral edema, wound discharge, increased GGT, increased lipase, increased amylase, increased blood bilirubin, increased transaminases, increased LDH, increased alkaline phosphatase, dizziness, headache, syncope, renal dysfunction, pruritus, rash, urticaria, contusion, bleeding after surgery, bleeding from the gastrointestinal tract, hematuria, bleeding from the reproductive system, epistaxis.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug and patients with active, clinically significant bleeding, such as intracranial hemorrhage, gastrointestinal bleeding.
Precautions: Renal failure, risk of hemorrhage, neuraxial anesthesia (epidural/spinal), women of childbearing age. Caution should be used if patients receive concomitant treatment with drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet aggregation inhibitors, or other antithrombotics.

Interactions

Rivaroxaban is not recommended in patients receiving concomitant systemic treatment with azole antifungals or HIV protease inhibitors. These drugs are potent inhibitors of CYP3A4 and P-gp. Therefore, these drugs may increase rivaroxaban plasma concentrations to a clinically relevant extent that may result in an increased risk of bleeding. Rivaroxaban can be taken with or without food.

ROMIPLOSTIM

Clue	Description	Indications	Route of administration and dosage
010.000.5624.00	INJECTABLE SOLUTION Each vial with powder contains: Romiplostin 375 µg. Container with a vial with powder (250 µg/0.5 mL reconstituted).	Treatment of adult patients and pediatric patients over 6 years of age with chronic idiopathic thrombocytopenic purpura refractory to conventional treatments and rescue therapies, and in non-splenectomized patients who have a contraindication for surgery.	Subcutaneous. Adults, and Children (>6 years of age and <18 years of age): Initial dose: 1 µg/Kg of body weight once a week. Dose adjustment: increments of 1 µg/Kg of body weight per week until reaching 9 / L. platelet count ÿ50 X 10 Maximum dose: 10 µg/Kg of body weight per week.

Generalities

Romiplostim is an Fc-peptide (peptide body) fusion protein that signals and activates intracellular transcription pathways through the thrombopoietin (TPO) receptor (also called cMpl) to increase platelet production. The peptide body molecule consists of an Fc domain of the human immunoglobulin IgG1, with each single-chain subunit covalently linked at the C terminus to a peptide chain containing two TPO receptor binding domains.

Risk in Pregnancy

c

Adverse effects

Bone marrow disorders, thrombocytopenia, angioedema, nausea, diarrhea, abdominal pain, constipation, dyspepsia, arthralgia, myalgia, muscle spasm, back pain, pain in extremities, bone pain, dizziness, migraine, paresthesia, insomnia , pulmonary embolism, pruritus, ecchymosis, rash.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug.
Precautions: Recurrence of thrombocytopenia and bleeding after completion of treatment, increase in reticulin in the bone marrow, progression of existing Myelodysplastic Syndromes (MDS), loss of response to romiplostim, effects of romiplostim on red and white blood cells.

Interactions

The medications used in the treatment of ITP in combination with romiplostim in clinical trials were corticosteroids, danazol and/or azathioprine, intravenous immunoglobulin (IVIG), and anti-D immunoglobulin. When romiplostim is combined with other medications for the treatment of ITP, platelet counts should be monitored to avoid platelet counts outside the recommended range.

Corticosteroids, danazol and azathioprine should be reduced or discontinued when administered in combination with romiplostim. When other treatments for ITP are reduced or stopped, platelet counts should be monitored to prevent them from falling outside the recommended range.

SIMOCTOCOG ALFA

Clue	Description	Indications	Route of administration and dosage
010.000.6216.00	INJECTABLE SOLUTION The vial with lyophilized powder contains: Simoctocog alfa 250 IU Vial container with 250 IU of lyophilized powder, a prefilled syringe with 2.5 mL of diluent and a sterile vial adapter for reconstitution and a butterfly needle	Treatment and prophylaxis of bleeding patients with in hemophilia A (congenital factor VIII deficiency).	Children and adults. Treatment of hemorrhage. Intravenous infusion. The dose depends on the type of bleeding episode or surgery to which the patient is subjected, considering the increase in the percentage of FVIII activity that is desired. The calculation is done with the following formula: Units required = body weight (kg) x desired factor VIII increase (%) (IU/dl) x 0.5 (IU/kg per IU/dL of FVIII) The frequency of administration should be oriented towards achieving clinical efficacy in each particular case. Prophylaxis. intravenous infusion Dose: 20 to 40 IU/kg body weight every 2 to 3 days In children, a higher dose or shorter frequency of administration may be required.
010.000.6217.00	INJECTABLE SOLUTION The vial with lyophilized powder contains: Simoctocog alfa 500 IU Vial container with 500 IU of lyophilized powder, a prefilled syringe with 2.5 mL of diluent and a sterile vial adapter for reconstitution and a butterfly needle.		
010.000.6218.00	INJECTABLE SOLUTION The vial with lyophilized powder contains: Simoctocog alfa 1000 IU Vial container with 1000 IU of lyophilized powder, a prefilled syringe with 2.5 mL of diluent and a sterile vial adapter for reconstitution and a butterfly needle.		
010.000.6219.00	INJECTABLE SOLUTION The vial with lyophilized powder contains: Simoctocog alfa 2000 IU Vial container with 2000 IU of lyophilized powder, a prefilled syringe with 2.5 mL of diluent and a sterile vial adapter for reconstitution and a butterfly needle		

Generalities

Simoctocog alfa is the first recombinant FVIII (rFVIII) without the ÿ domain of the protein (FVIII), produced in the human HEK cell line, cultured in a medium free of human or animal proteins and without fusion to other human or animal proteins. The production process involves the transfection of HEK293F cells with adenovirus that contains a plasmid without the ÿ domain of FVIII, these cells are subsequently expanded and optimized to have maximum expression of FVIIII. A small peptide of 16 amino acids is chained to the heavy and light chain of rFVIII, which allows it to bind quickly and completely to endogenous VWF.

Risk in Pregnancy C

Adverse effects

Hypersensitivity or allergic reactions (which may include angioedema, burning and pruritus at the infusion site, chills, flushing, hives, headache, hypotension, lethargy, nausea, restlessness, tachycardia, chest tightness, tingling sensation, vomiting, wheezing) with factor VIII preparations and in some cases may progress to severe anaphylaxis (including shock).

Patients with hemophilia A may develop neutralizing antibodies (inhibitors) to factor VIII. If these inhibitors (neutralizing antibodies) are produced, the disease will manifest as an insufficient clinical response. In such cases, it is recommended to contact a specialized hemophilia center.

Contraindications and Precautions

Contraindicated in hypersensitivity to the active product or any of the components of the formula. In patients without prior exposure to FVIII, the development of antibodies that inhibit FVIII activity should be monitored, particularly during the first 50 days of exposure to Simoctocog alfa.

Interactions

No interaction studies have been performed with Simoctocog alfa.

TICAGRELOR

Clue	Description	Indications	Route of administration and dosage
010.000.5730.01	TABLET Each tablet contains: Ticagrelor 90 mg. Package with 60 tablets.	Adults with syndrome Acute coronary artery with myocardial infarction requiring percutaneous coronary intervention or aorto-coronary bypass bridges.	Oral. Adults: 90 mg every 12 hours. Start treatment with a single loading dose of 180 mg and then continue with a maintenance dose of 90 mg every 12 hours. In turn, take acetylsalicylic acid from 75 mg to 150 mg, every 24 hours.

Generalities

Ticagrelor, a member of the cyclopentyltriazolpyrimidines (CPTP) chemical class, is a selective and reversible adenosine diphosphate (ADP) receptor antagonist that acts at the ADP P2Y12 receptor and may prevent ADP-mediated platelet activation and aggregation. . Ticagrelor is orally active and interacts reversibly with the platelet ADP receptor P2Y12. Ticagrelor does not interact with the specific ADP binding site, but rather its interaction with the platelet receptor prevents signal transduction of the P2Y12 ADP receptor.

Risk in Pregnancy C

Adverse effects

Hyperuricemia, headache, dizziness, vertigo, dyspnea, epistaxis, abdominal pain, constipation, diarrhea, dyspepsia, hemorrhage b

gastrointestinal , nausea, vomiting, subcutaneous or dermal bleeding, rash, pruritus, urinary tract bleeding, increased blood creatinine , post-procedure bleeding.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug, cases of active pathological bleeding, history of intracranial hemorrhage or severe liver failure.
Precautions: Patients prone to bleeding (e.g., due to recent trauma, recent surgery, recent or active gastrointestinal bleeding, or moderate hepatic insufficiency). Patients with active pathological bleeding and in those with a history of intracranial hemorrhage and severe liver failure. Concomitant administration of medicinal products that may increase the risk of bleeding (for example, non-steroidal anti-inflammatory drugs (NSAIDs), oral anticoagulants and/or fibrinolytics within 24 hours of Ticagrelor administration).

Interactions

The concomitant use of ticagrelor and drugs metabolized by the CYP3A4 enzyme may modify the concentrations of the latter: ketoconazole, diltiazem, rifampicin, dexamethasone, phentoin, carbamazepine, phenobarbital, simvastatin and atorvastatin.

TUROCTOCOG ALFA (HUMAN COAGULATION FACTOR VIII OF ORIGIN RECOMBINANT DNA)

Clue	Description	Indications	Route of administration and dosage
010.000.6061.00	INJECTABLE SOLUTION Each vial with lyophilized powder contains: Turoctocog alfa 250 IU Package with a vial with lyophilized powder, a prefilled syringe with 4 mL of diluent with or without administration equipment.	Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital deficiency of factor VIII).	Intravenous. Adults and children: Request: Units are calculated by multiplying body weight (kg) x desired factor VIII increase (%) (IU/dL) x 0.5 (IU/kg times IU/dL).
010.000.6062.00	INJECTABLE SOLUTION Each vial with lyophilized powder contains: Turoctocog alfa 500 IU Package with a vial with lyophilized powder, a prefilled syringe with 4 mL of diluent with or without administration equipment.		Prophylaxis: 20-40 IU per kg of body weight every other day or 20-50 IU per kg of body weight three times a week Adjust the dose according to therapeutic efficacy.
	INJECTABLE SOLUTION		

010.000.6063.00	Each vial with lyophilized powder contains: Turoctocog alfa 1,000 IU Package with a vial with lyophilized powder, a prefilled syringe with 4 mL of diluent with or without administration equipment.		

Generalities

Human coagulation factor VIII with truncated B domain, of recombinant DNA origin expressed in Chinese Hamster Ovary (CHO) cells. Turoctocog alfa is a purified protein containing 1,445 amino acids with an approximate molecular mass of 166 kDA. This glycoprotein has the same structure as human factor VIII when activated, and post-translational modifications similar to those of the plasma-derived molecule.

Risk in Pregnancy c

Adverse effects

Insomnia, headache, dizziness, sinus tachycardia, hypertension, lymphedema, elevated liver enzymes, rash, musculoskeletal stiffness, arthropathy, pain in extremities, musculoskeletal pain, erythema, extravasation, pruritus, fatigue, sensation of heat, peripheral edema, fever, increased heart rate

Contraindications and Precautions

Contraindications: Hypersensitivity to the biological.
Precautions: Development of neutralizing antibodies (inhibitors) against recombinant factor VIII.

Interactions

No interaction studies have been performed.

WARFARINE

Clue	Description	Indications	Route of administration and dosage
010.000.0623.00	TABLET Each tablet contains: Warfarin sodium 5 mg. Package with 25 tablets.	Prophylaxis and treatment of: Thromboembolic conditions. Deep venous thrombosis. Pulmonary thromboembolism.	Oral. Adults and kids older than 12 years old: 10 to 15 mg per day for two to five days, then 2 to 10 mg per day, according to the prothrombin time.

Generalities

Coumarin anticoagulant that inhibits the effect of vitamin K and consequently decreases the formation of coagulation factors II (prothrombin), VII, IX, X and proteins C and S.

Risk in Pregnancy x

Adverse effects

The most common and important risk is hemorrhage (6 to 29%); that occurs anywhere in the body. Nausea, vomiting, diarrhea, alopecia, dermatitis.

Contraindications and Precautions

Contraindications: Hypersensitivity to the drug. Pregnancy, active bleeding, recent surgery or trauma, active peptic ulcer, threatened abortion, blood dyscrasias, bleeding tendency, severe arterial hypertension.

Precautions: The dose should be lower in elderly and debilitated patients.

Interactions

Most medications increase or decrease the anticoagulant effect of warfarin, so it is necessary to readjust the dose based on the prothrombin time each time the drug is added or stopped.
medicine.