**CISPLATINO KEMEX**
**Cisplatin 10, 25, and 50 mg Lyophilized Powder for Injection**
**Cisplatin 10 and 50 mg Solution for Injection**

**Prescription only** **Made in Argentina**

**QUALI-QUANTITATIVE FORMULA**

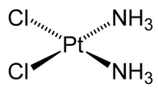
| **Lyophilized Powder for Injection** | **10 mg** | **25 mg** | **50 mg** |
|---|---|---|---|
| Each vial contains: | | | |
| Cisplatin | 10 mg | 25 mg | 50 mg |
| Sodium chloride | 90 mg | 225 mg | 450 mg |
| Mannitol | 100 mg | 250 mg | 500 mg |

| **Solution for Injection** | **10 mg** | **50 mg** |
|---|---|---|
| **Each vial contains:** | | |
| Cisplatin | 10 mg | 50 mg |
| Sodium chloride | 90 mg | 450 mg |
| Hydrochloric Acid qs pH | 3.4 | 3.4 |
| Water for Injection qs | 10 ml | 50 ml |

**THERAPEUTIC ACTION**
Antineoplastic

**ATC Classification:** L01XA01

**Structural and Molecular Formula:**




**Formula:** $H_6Cl_2N_2Pt$

**INDICATIONS**
Indicated in the treatment of the following conditions:
- Advanced or metastatic testicular cancer
- Advanced or metastatic ovarian cancer
- Advanced or metastatic bladder carcinoma
- Advanced or metastatic squamous cell carcinoma of the head and neck
- Advanced or metastatic lung carcinoma
- Advanced or metastatic small cell lung carcinoma
- Cisplatin is indicated in the treatment of cervical carcinoma in combination with other antineoplastic agents or radiotherapy.
- Cisplatin can be used as monotherapy or in combination treatments.

**PHARMACOLOGICAL ACTION / PROPERTIES**
**Pharmacological action:**
Inhibits DNA synthesis by producing cross-links in DNA. RNA and protein synthesis are inhibited to a lesser extent.
Although the main mechanism of action of cisplatin appears to be the inhibition of DNA synthesis, its antineoplastic activity includes other mechanisms, such as increasing tumor immunogenicity. The lytic properties of cisplatin are comparable to those of alkylating agents. Cisplatin offers immunosuppressive, radiosensitizing, and antibacterial properties. Cisplatin does not appear to be cell cycle-specific. The cytotoxic activities of cisplatin occur through binding to all DNA bases, with a preference for the N-7 position of guanine and adenosine.

**Pharmacokinetic Properties:**
Following intravenous administration, cisplatin rapidly distributes to all tissues but penetrates very little into the central nervous system. The highest concentrations are reached in the liver, kidneys, bladder, muscle tissue, skin, testicles, prostate, pancreas, and spleen.
After intravenous administration, the elimination of unbound and filterable cisplatin occurs in a biphasic manner, with an initial half-life of 10-20 minutes and a terminal half-life of 32-53 minutes, respectively. The elimination of the total amount of platinum occurs in a triphasic manner, with half-lives of 14 minutes, 274 minutes, and 53 days, respectively.
Cisplatin binds to plasma proteins by 90%.
Excretion occurs primarily through the urine: 27-43% of the administered dose is recovered in the urine within the first 5 days after treatment. Platinum is also excreted in bile.

**DOSAGE / ADMINISTRATION**
Cisplatin 1 mg/ml concentrate for solution for infusion should be diluted before administration. The diluted solution should only be administered intravenously by infusion. Aluminum-containing materials that may come into contact with cisplatin (intravenous infusion equipment, needles, catheters, syringes) should be avoided during administration.

**Adults and children:**
The dosage of cisplatin depends on the primary disease, the expected response, and whether cisplatin is used as monotherapy or in combination with different antineoplastic agents. The dosage guidelines are applicable for both adults and children.

In monotherapy, the following two regimens are recommended:
- Single dose of 50 to 120 mg/m$^2$ of body surface area every 3-4 weeks;
- 15 to 20 mg/m$^2$/day for 5 days, every 3-4 weeks.

If cisplatin is used in combination chemotherapy, the cisplatin dose should be reduced. A common dose is 20 mg/m$^2$ or more once every 3-4 weeks. For the treatment of cervical cancer, cisplatin is used in combination with radiotherapy. A common dose is 40 mg/m$^2$ weekly for 6 weeks.
In patients with renal dysfunction or myelosuppression, the dose should be reduced. The cisplatin solution for infusion prepared according to the instructions should be administered by intravenous infusion over a period of 6 to 8 hours.
Adequate hydration should be maintained from 2 to 12 hours before administration and for at least 6 hours after cisplatin administration. Hydration is necessary to induce sufficient diuresis during and after cisplatin treatment. It is performed by intravenous infusion of one of the following solutions: 0.9% sodium chloride solution; Mixture of 0.9% sodium chloride solution and 5% glucose solution.

*Pre-treatment hydration with cisplatin:*
Intravenous infusion of 100-200 ml/hour over a period of 6 to 12 hours, with a total volume of at least 1 liter.

*Post-completion hydration after cisplatin administration:*
Intravenous infusion of an additional 2 liters at a rate of 100-200 ml/hour over a period of 6 to 12 hours.
Forced diuresis may be necessary if the urine volume is less than 100-200 ml/hour after hydration. Forced diuresis can be performed by intravenous administration of 37.5 g of mannitol as a 10% solution (375 ml of 10% mannitol solution), or by administering a diuretic if renal function is normal. Administration of mannitol or a diuretic is also necessary when the administered dose of cisplatin exceeds 60 mg/m² of body surface area.
It is necessary for the patient to drink large amounts of fluids in the 24 hours following cisplatin infusion to ensure sufficient diuresis.

**ADMINISTRATION METHOD**
**Product Preparation and Handling**
As with all antineoplastic products, caution is required in the handling of cisplatin. It should be diluted before use. Dilution should be done under aseptic conditions by trained personnel in a specifically designated area. Protective gloves should be worn, and precautions should be taken to avoid contact with the skin and mucous membranes. In case of skin contact, wash immediately with soap and water. Skin contact may cause tingling, burns, and redness. In case of mucous membrane contact, rinse thoroughly with abundant water. Inhalation may cause shortness of breath, chest pain, throat irritation, and nausea. Pregnant women should avoid contact with cytostatics. Organic waste material and vomit should be carefully disposed of.
If the solution is cloudy or contains a deposit that does not dissolve, the vial should be discarded. Damaged vials should be treated with the same precautions as contaminated waste. Contaminated waste should be placed in specific waste containers.

**Preparation for Intravenous Administration**
**Lyophilized Powder for Injection**
Cisplatin Lyophilized Powder should be reconstituted by dissolving the contents of the vial in the appropriate amount of Sterile Water for Injection. Each ml of the resulting solution will contain 1 mg of cisplatin. The reconstituted powder in Sterile Water for Injection.
The recommended reconstitution results in a clear, colorless solution. The reconstituted solution should be used only intravenously and should be administered by IV infusion over 6 to 8 hours.
Once reconstituted, take the required amount of solution from the vial and dilute it with at least 1 liter of the following solutions:
- 0.9% sodium chloride solution
- mixture of 0.9% sodium chloride solution/5% glucose solution (resulting final concentrations: 0.45% sodium chloride, 2.5% glucose)
- 0.9% sodium chloride and 1.875% mannitol solution for injection
- 0.45% sodium chloride, 2.5% glucose, and 1.875% mannitol solution for injection

Always inspect the solution before use. If the solution is not transparent or if insoluble precipitates form, the solution should not be used. Only clear solutions without visible particles should be administered.

***Do not come into contact with injection instruments containing aluminum.***
***Do not administer undiluted.***

**Disposal**
All materials used for preparation and administration or those that have come into contact with cisplatin in any way should be disposed of according to local cytotoxic waste requirements. This will help protect the environment.

**CONTRAINDICATIONS**
Cisplatin is contraindicated in patients:
• With hypersensitivity to cisplatin or other platinum-containing medications or any of the excipients
• With pre-existing renal insufficiency*
• With dehydration (hydration is required before and after administration to prevent severe renal dysfunction)
• With myelosuppression
• With pre-existing hearing impairment*
• With cisplatin-induced neuropathy
• During lactation
• In combination with live attenuated vaccines, including yellow fever vaccine
• In combination with prophylactic phenytoin use
*due to the nephrotoxic and neurotoxic (specifically, ototoxic) nature of cisplatin. These toxicities may be cumulative in the presence of these disorders.

**WARNINGS**
Cisplatin reacts with metallic aluminum and forms a black platinum precipitate. Needles, catheters, syringes, and all intravenous administration materials containing aluminum should be avoided.
Cisplatin should only be administered under the supervision of a qualified oncology physician experienced in the use of antineoplastic chemotherapy. Proper diagnosis and treatment conditions are necessary for appropriate control and management of the treatment and its complications.
Cisplatin has demonstrated cumulative ototoxic, nephrotoxic, and neurotoxic effects. The toxicity caused by cisplatin may be increased when combined with other medications that are toxic to these organs or systems.
Patients of both sexes should use contraceptive methods during cisplatin treatment and for at least 6 months afterward.
*1. Nephrotoxicity*
Cisplatin causes severe cumulative nephrotoxicity. A diuresis rate of 100 ml/hour or higher tends to minimize cisplatin nephrotoxicity. This can be achieved by pre-hydration with 2 liters of an appropriate intravenous solution and similar hydration post-cisplatin (recommended rate of 2,500 ml/m$^2$/24 hours). If intense hydration is insufficient to maintain adequate diuresis, an osmotic diuretic (e.g., mannitol) may be administered. Hyperuricemia and hypoalbuminemia may predispose to cisplatin-induced nephrotoxicity.
*2. Neuropathies*
Severe cases of neuropathies have been reported, which may be irreversible and manifest as paresthesia, areflexia, loss of proprioception, and vibration sensation. Loss of motor function has also been described. Regular neurological examinations should be performed, and caution should be exercised in patients with peripheral neuropathy not caused by cisplatin.
*3. Ototoxicity*
Ototoxicity has been observed in up to 31% of patients treated with a single dose of cisplatin 50 mg/m$^2$, manifested as tinnitus and/or high-frequency hearing loss (4,000 to 8,000 Hz range). Occasionally, there may be a reduction in the ability to hear conversation tones. The ototoxic effect may be more pronounced in children receiving cisplatin. Hearing loss can be unilateral or bilateral and is more frequent and intense with repeated doses; however, cases of deafness after the initial dose of cisplatin are rare. Ototoxicity may be increased with prior concurrent cranial irradiation and may be related to the peak plasma concentration of cisplatin. It is unknown if cisplatin-induced ototoxicity is reversible. Careful monitoring with audiometry should be conducted before initiating treatment and before subsequent doses of cisplatin. Cases of vestibular toxicity have also been reported.
Before, during, and after cisplatin administration, the following organ functions should be assessed:
- Renal function
- Hepatic function
- Hematopoietic function (red blood cell, white blood cell, and platelet counts)
- Serum electrolytes (calcium, sodium, potassium, magnesium)

These assessments should be repeated weekly throughout the duration of cisplatin treatment.
Repeat cisplatin treatment should be delayed until the following parameters return to normal values:
- Serum creatinine < 130 µmol/L (1.5 mg/dL)
- Urea < 25 mg/dL
- White blood cell count > 4,000/µL (> 4.0 x 10$^9$/L)
- Platelet count > 100,000/µL (> 100 x 10$^9$/L)
- Audiogram: within normal range.

*4. Allergic reactions*
Like other platinum-based products, hypersensitivity reactions can occur, mostly during infusion, and require suspension of treatment and appropriate symptomatic management. Cross-reactivity has been described, including fatal cases, with all platinum compounds. Anaphylactic reactions to cisplatin have been observed. These reactions can be controlled with the administration of antihistamines, adrenaline, and/or glucocorticoids.
*5. Liver function and hematological profile*
Hematological profile and liver function should be monitored at regular intervals.
*6. Carcinogenic potential*
In isolated cases, the appearance of acute leukemia has been reported in humans coinciding with the use of cisplatin, often in conjunction with other leukemogenic agents. Cisplatin is a bacterial mutagen causing chromosomal aberrations in animal cell cultures. The occurrence of tumors is possible but not proven. Cisplatin is teratogenic and embryotoxic in mice.
*7. Injection site reactions*
Reactions at the injection site may occur during cisplatin administration. Considering the possibility of extravasation, close monitoring of the infusion site is recommended to detect possible infiltration during drug administration. Currently, there is no specific treatment for extravasation reactions.

*This cytostatic agent has shown more notable toxicity than that commonly observed with antineoplastic chemotherapy. Nephrotoxicity, which is particularly cumulative, is severe and requires special precautions during administration. Nausea and vomiting can be intense and require appropriate antiemetic treatment. Strict monitoring of ototoxicity, myelosuppression, and anaphylactic reactions should also be carried out.*

**PRECAUTIONS:**
**Interaction with other medications and other forms of interaction:**
Simultaneous use of myelosuppressive agents or radiation will enhance the myelosuppressive effects of cisplatin.
The occurrence of cisplatin-induced nephrotoxicity may be intensified by concomitant treatment with antihypertensive drugs containing furosemide, hydralazine, diazoxide, and propranolol.

**Nephrotoxic substances:**
Concomitant administration of nephrotoxic medications (e.g., cephalosporins, aminoglycosides, amphotericin B, or contrast media) or ototoxic medications (e.g., aminoglycosides) will potentiate the toxic effects of cisplatin on the kidneys. Caution is advised during or after cisplatin treatment with substances primarily eliminated by the renal route, such as cytostatic agents like bleomycin and methotrexate, as renal elimination may be reduced.
Cisplatin administered in combination with bleomycin and vinblastine can result in Raynaud's phenomenon.
The nephrotoxicity of ifosfamide may be increased when used with cisplatin or in patients who have previously received cisplatin.
A reduction in lithium blood levels has been observed in some cases after treatment with cisplatin combined with bleomycin and etoposide. Therefore, lithium levels should be monitored.
Dose adjustment of allopurinol, colchicine, probenecid, or sulfinpyrazone may be necessary when used concomitantly with cisplatin, as cisplatin causes an increase in serum uric acid concentration.
Cisplatin administered in combination with bleomycin and vinblastine can result in Raynaud's phenomenon.
In a study of cancer patients with metastatic or advanced tumors, docetaxel in combination with cisplatin induced more severe neurotoxic effects (dose-related and sensory) than both drugs administered alone at similar doses.
Chelating agents such as penicillamine may decrease the effectiveness of cisplatin.
Excessive immunosuppression with the risk of lymphoproliferation may occur with concurrent use of cisplatin and cyclosporine.

**Ototoxic substances:**
Concomitant administration of ototoxic medications (e.g., aminoglycosides, loop diuretics) will enhance the toxic effect of cisplatin on auditory function. Except in patients receiving cisplatin doses greater than 60 mg/m$^2$ and whose diuresis is less than 1,000 mL in 24 hours, forced diuresis with loop diuretics should not be applied due to the potential for renal injury and ototoxicity.
Ifosfamide may increase hearing loss due to cisplatin.

**Live attenuated vaccines:**
Yellow fever vaccine is strictly contraindicated due to the risk of life-threatening systemic illness. In consideration of the risks of disseminated disease, an inactivated vaccine is recommended if available.

**Oral anticoagulants:**
During simultaneous use of oral anticoagulants, periodic INR monitoring is recommended.

**Antihistamines, phenothiazines, and others:**
Simultaneous use of antihistamines, buclizine, cyclizine, loxapine, meclozine, phenothiazines, thioxanthenes, or trimethobenzamide may mask symptoms of ototoxicity (such as dizziness and tinnitus).

**Anticonvulsant substances:**
Serum concentrations of anticonvulsants may remain at subtherapeutic levels during cisplatin treatment. Cisplatin may reduce the absorption of phenytoin, which can impair epilepsy control if phenytoin is being administered as treatment at that time. Initiation of new anticonvulsant treatment with phenytoin is strictly contraindicated during cisplatin treatment.

**Combination of pyridoxine + altretamine:**
In a randomized study with patients with advanced ovarian carcinoma, treatment response was compromised by the simultaneous administration of cisplatin and altretamine (hexamethylmelamine).

**Paclitaxel:**
Treatment with cisplatin prior to paclitaxel infusion may reduce the elimination of paclitaxel by 33%, potentially intensifying neurotoxicity.

**Fertility, pregnancy and lactation:**
Cisplatin can be toxic to the fetus if administered to a pregnant woman. Animal studies have

shown reproductive toxicity and transplacental carcinogenicity. Patients of both sexes should take appropriate measures to avoid pregnancy during treatment with cisplatin and for at least 6 months thereafter. Genetic counseling is recommended if patients wish to have children after completing treatment. Since cisplatin treatment can cause irreversible infertility, men who wish to conceive in the future should seek advice on sperm cryopreservation before treatment.

**Lactation:**
Cisplatin is excreted in breast milk. Breastfeeding is contraindicated during treatment with cisplatin.

**Effects on ability to drive and use machines:**
No studies have been conducted on the effects on the ability to drive and use machines. However, the profile of adverse reactions (central nervous system and special senses) may have a slight or moderate influence on patients' ability to drive and use machines. Patients experiencing these adverse reactions (e.g., drowsiness or vomiting) should avoid driving and using machines.

**Drug-laboratory test interactions:**
**With physiological values:**
Blood concentrations of blood urea nitrogen (BUN) and serum creatinine, serum uric acid concentrations (may be increased, indicating nephrotoxicity), creatinine clearance, serum calcium concentrations, serum magnesium concentrations, serum phosphate concentrations, and serum potassium concentrations (may decrease due to actual toxicity).

**Carcinogenicity:**
It is one of the side effects associated with this agent. The dose and duration of therapy effects are also unknown; however, risks increase with long-term use.

**Mutagenicity:**
Cisplatin is mutagenic in bacteria and has been shown to cause chromosomal aberrations in animal cells in tissue culture.

**Use in pediatrics:**
Toxic effects of cisplatin may be more severe in children.

**Dental considerations:**
The bone marrow depressant effects of cisplatin may result in increased incidence of microbial infection. Dental work, if possible, should be completed before the initiation of therapy or reserved until blood counts return to normal. Patients should be instructed in oral hygiene during treatment, including care in the use of topicals, toothpastes, etc. Cisplatin may also rarely cause stomatitis associated with significant discomfort.

**ADVERSE REACTIONS / SIDE EFFECTS:**
Adverse reactions depend on the dose used and may have cumulative effects.
The most frequently reported adverse reactions (>10%) with cisplatin were hematological (leucopenia, thrombocytopenia, and anemia), gastrointestinal (anorexia, nausea, vomiting, and diarrhea), ear disorders (hearing impairment), renal disorders (renal failure, nephrotoxicity, hyperuricemia), and fever.
Serious toxic effects on the kidneys, bone marrow, and ears have been reported in up to one-third of patients treated with a single dose of cisplatin; the effects are generally dose-related and cumulative. Ototoxicity may be more severe in children.
Frequencies are defined using the following convention:
Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), frequency not known (cannot be estimated from available data).
Hypersensitivity reactions such as rash, urticaria, erythema, or allergic pruritus may occur.

**Table of serious adverse reactions described during clinical experience or post-marketing (MedDRA terms).**

| Organ or system | Frequency | MedDRA Term |
|---|---|---|
| Infections and infestations | Unknown | Infections[a] |
| | Common | Septicemia |
| Blood and lymphatic system disorders | Very common | Bone marrow failure, thrombocytopenia, leukopenia, anemia |
| | Unknown | Coombs-positive hemolytic anemia |
| Benign, malignant, and unspecified neoplasms | Rare | Acute leukemia |
| Immune system disorders | Uncommon | Anaphylactoid reaction[b] Hypersensitivity reactions such as skin rash, urticaria, erythema, or allergic pruritus may occur |
| Endocrine disorders | Unknown | Elevated blood amylase, inappropriate secretion of antidiuretic hormone |
| Metabolic and nutritional disorders | Unknown | Dehydration, hypokalemia, hypophosphatemia, hypocalcemia, tetany, muscle spasms, and/or electrocardiogram abnormalities as a result of kidney injury caused by cisplatin by reducing tubular reabsorption of cations. Hypercholesterolemia. Increased blood amylase |
| | Uncommon | Hypomagnesemia |
| | Very rare | Increased blood iron |
| | Very common | Hyponatremia |
| Disorders of the nervous system | Unknown | Stroke, hemorrhagic stroke, ischemic stroke, ageusia, cerebral arteritis, Lhermitte's sign, myelopathy, neurovegetative neuropathy |
| | Rare | Seizure, peripheral neuropathy, leukoencephalopathy, reversible posterior leukoencephalopathy syndrome |
| Eye disorders | Unknown | Blurred vision, acquired color blindness, cortical blindness, optic neuritis, papilledema, retinal pigmentation |
| Ear and labyrinth disorders | Uncommon | Ototoxicity |
| | Unknown | Tinnitus, hearing loss |
| | Rare | Patients may lose the ability to maintain a normal conversation. Cisplatin-induced hearing loss can be severe in children and the elderly |
| Cardiac disorders | Unknown | Cardiac disorder |
| | Common | Arrhythmia, bradycardia, tachycardia |
| | Rare | Myocardial infarction |
| | Very rare | Cardiac arrest |
| Vascular disorders | Unknown | Thrombotic microangiopathy (hemolytic uremic syndrome), Raynaud's syndrome |
| | Common | Injection site phlebitis |
| Gastrointestinal disorders | Unknown | Vomiting, nausea, anorexia, hiccups, diarrhea |
| | Uncommon | Metallic discoloration of the gums |
| | Rare | Stomatitis |
| Hepatobiliary disorders | Unknown | Hepatic impairment, increased liver enzymes |
| | Rare | Reduced blood albumin levels |
| Respiratory, thoracic, and mediastinal disorders | Common | Dyspnea, pneumonia, respiratory failure |
| | Unknown | Pulmonary embolism |
| Skin and subcutaneous tissue disorders | Unknown | Skin rash, alopecia |
| Musculoskeletal and connective tissue disorders | Unknown | Muscle spasms |
| Renal and urinary disorders | Unknown | Acute renal failure, renal insufficiency[c], renal tubular disorders Very common Hyperuricemia |
| | Very common | Hyperuricemia |
| Reproductive system and breast disorders | Uncommon | Abnormal spermatogenesis and ovulation, painful gynecomastia |
| General disorders and administration site conditions | Unknown | Fever (very common), asthenia, malaise, extravasation at the injection site |

**Frequency source: Internal technical data sheet (CCDS, CompanyCore Data Sheet) of cisplatin injection, BMS*

*Pharmacovigilance and epidemiology, August 2, 2010. Frequencies not described in the CCDS have been added from the evaluation report.*
*a: Infectious complications have led to death in some patients.*
*b: Symptoms described for anaphylactic reaction such as facial edema (TP), wheezing, bronchospasm, tachycardia, and hypotension will be included in parentheses for anaphylactic reaction in the adverse events frequency table.*
*c: Increased BUN, serum creatinine, and uric acid and/or reduced creatinine clearance are included in renal insufficiency.*
*d: Local tissue toxicity, including soft tissue cellulitis, fibrosis, necrosis (frequent), pain (frequent), edema (frequent), and erythema (frequent) as a result of extravasation.*

**OVERDOSAGE**
Symptoms of overdose involve the aforementioned side effects but in an excessive manner. Effective hydration and osmotic diuresis may contribute to reducing toxicity if used immediately after overdose.

**In case of an overdose, seek the nearest hospital or contact poison control centers:**
Dr. Ricardo Gutiérrez Children's Hospital: Tel.: (011) 4962-6666/2247
Pedro de Elizalde Hospital: Tel.: (011) 4300-2115 / 4362-6063
Dr. Juan A. Fernández Hospital: Tel.: (011) 4808-2655
Dr. A. Posadas Hospital: Tel.: (011) 4654-6648/ 4658-7777 / 0800-3330160

**PRESENTATIONS**
Cisplatino Kemex 10, 25, and 50 mg - Lyophilized Powder for Injection
Package containing 1, 5, 10, 50, and 100 units, with the last three being for exclusive use in hospitals.
Cisplatino Kemex 10 and 50 mg - Injectable Solution
Package containing 1, 5, 10, 50, and 100 units, with the last three being for exclusive use in hospitals.

**STORAGE**
Lyophilized Powder for Injection:
The reconstituted solution is stable for 24 hours at room temperature, protected from light. Do not store diluted solutions in the refrigerator.

**STORE AT TEMPERATURE FROM 15 °C TO 30 °C.**
**PROTECT FROM LIGHT. DO NOT REFRIGERATE.**

**KEEP OUT OF REACH OF CHILDREN.**
**FOR ANY DOUBTS, CONSULT YOUR DOCTOR.**
**Do not use after the expiration date.**

**"This medicine should be used exclusively under medical prescription and cannot be repeated without a new medical prescription."**

Medicinal product authorized by the Ministry of Health (ANMAT).
Certificate No. 47,683

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