INSTRUCTION
for medical use of the medicinal product

PARAPLEXIN®

Composition:
Active substance: ipidacrine hydrochloride monohydrate;
1 ml of solution contains 5 mg or 15 mg of ipidacrine hydrochloride monohydrate, calculated as anhydrous substance;
Excipient: water for injections.

Pharmaceutical form: Injection solution.
Physical and chemical properties: A clear, colorless liquid.

Pharmacotherapeutic group: Other agents acting on the nervous system. Parasympathomimetics. Anticholinesterase agents. ATC code N07AA.

Pharmacological properties:
Pharmacodynamics:
Paraplexin® is a reversible inhibitor of cholinesterase.
Paraplexin® exerts a direct stimulating effect on the transmission of impulses through nerve fibers, interneuronal and neuromuscular synapses of the peripheral and central nervous system (CNS).
The pharmacological action of Paraplexin® is based on a combination of two mechanisms of action:
- Blockage of potassium channels in the membrane of neurons and muscle cells;
- Reversible inhibition of cholinesterase in synapses.
Paraplexin® enhances the action on smooth muscles not only of acetylcholine but also of adrenaline, serotonin, histamine, and oxytocin.
The medicinal product exhibits the following pharmacological effects:
- Restores and stimulates the transmission of impulses in the nervous system and neuromuscular transmission;
- Enhances the contractility of smooth muscle organs under the influence of all antagonists of acetylcholine, adrenaline, serotonin, histamine, and oxytocin receptors, except for potassium chloride;
- Improves memory, inhibits the progressive development of dementia;
- Restores the transmission of impulses in the peripheral nervous system, disrupted due to various factors such as trauma, inflammation, the action of local anesthetics, some antibiotics, potassium chloride, toxins;
- Moderately stimulates the CNS in combination with the manifestation of individual sedative effects;
- Exhibits an analgesic effect;
- Exhibits an antiarrhythmic effect.
The medicinal product Paraplexin® does not have teratogenic, embryotoxic, mutagenic, carcinogenic, allergenic, or immunotoxic effects. Also, this medicinal product does not affect the endocrine system.

Pharmacokinetics:
Paraplexin® is rapidly absorbed after subcutaneous or intramuscular administration. The maximum concentration in the blood is reached within 25–30 minutes, with 40–50% of the active substance binding to plasma proteins. Paraplexin® quickly penetrates into tissues, with a half-life of 40 minutes in the elimination phase. It is metabolized in the liver and excreted by the kidneys, as well as externally (through the gastrointestinal tract). The half-life after parenteral administration of the drug is 2–3 hours. Excretion mainly occurs through tubular secretion, and only one-third of the dose is excreted by glomerular filtration. After parenteral administration, 34.8% of the drug dose is excreted in the urine unchanged.

Clinical Characteristics:
Indications:
Diseases of the peripheral nervous system: mono- and polyneuropathy, polyradiculopathy, myasthenia, and myasthenic syndrome of various etiologies.
Central nervous system (CNS) diseases: bulbar paralysis and paresis; recovery period of organic CNS damage accompanied by motor disorders.

Contraindications:
Increased sensitivity to ipidacrine.
Epilepsy.
Extrapyramidal disorders with hyperkinesis.
Angina.
Marked bradycardia.
Bronchial asthma.
Vestibular disorders.
Mechanical obstruction of the intestines and urinary tract.
Peptic ulcer disease of the stomach or duodenum in the acute phase.
Pregnancy.
Breastfeeding period.

Interactions with other medicinal products and other forms of interaction:
Paraplexin® enhances the sedative effect in combination with CNS depressants. The action and side effects are intensified when used concurrently with other cholinesterase inhibitors and m-cholinomimetic agents. In patients with myasthenia, there is an increased risk of developing a "cholinergic" crisis if Paraplexin® is used simultaneously with cholinergic agents. The risk of developing bradycardia increases if β-blockers were used before starting treatment with Paraplexin®.
Paraplexin® can be used in combination with nootropic drugs.
Alcohol enhances the side effects of the drug.

***Special Instructions*:**
The drug should be used with caution in patients with a history of peptic ulcer disease of the stomach and duodenum, respiratory diseases, including acute respiratory diseases, cardiovascular diseases not related to coronary pain, and thyrotoxicosis.

Use during pregnancy or breastfeeding:

Paraplexin® increases uterine tone and may cause premature labor; therefore, its use during pregnancy is contraindicated.
The use of the drug during the breastfeeding period is contraindicated.

The ability to influence the reaction rate when driving vehicles or other mechanisms:
During treatment, it is necessary to refrain from driving a car and from potentially dangerous types of activities that require increased concentration of attention and speed of psychomotor reactions.

Method of use and doses:
The injection solution should be administered subcutaneously or intramuscularly. The dose and duration of treatment should be determined individually depending on the severity of the disease.
Diseases of the peripheral nervous system
Mono- and polyneuropathy of various origins: administer subcutaneously or intramuscularly 5–15 mg once or twice a day, the treatment course lasts 10–15 days (in severe cases – up to 30 days); thereafter, treatment should continue with the tablet form of the drug.
Myasthenia and myasthenic syndrome: administer subcutaneously or intramuscularly 5–30 mg 1-3 times a day, transitioning later to the tablet form. The total treatment course is 1–2 months. If necessary, treatment can be repeated several times with a break of 1–2 months between courses.
Diseases of the CNS
Bulbar paralysis and paresis: administer subcutaneously and intramuscularly 5–15 mg once or twice a day, the treatment course is 10–15 days, transitioning to the tablet form if possible.
Recovery period in organic CNS damage: administer intramuscularly 10–15 mg once or twice a day, the treatment course lasts up to 15 days, then if possible, continue 1-2 times a day.

Children:
There is no systematic data on the use of the parenteral form of Paraplexin® in children (under 18 years of age), therefore this medicinal product should not be used in children.

Overdose:
Symptoms:
Severe overdose may lead to a "cholinergic crisis," characterized by bronchospasm, tearfulness, increased sweating, pupil constriction, nystagmus, increased gastrointestinal peristalsis, spontaneous defecation and urination, vomiting, jaundice, bradycardia, intracardiac conduction disorders, arrhythmia, lowered blood pressure, agitation, anxiety, excitement, fear, ataxia, seizures, coma, speech disturbances, drowsiness, general weakness.
Treatment: symptomatic therapy should be used, applying m-cholinoblockers: atropine, cycloplegia, metacin.

Side effects:
Paraplexin®, like other drugs, may cause side effects, although not all patients will experience them.
The frequency of side effects according to the MedDRA classification:
very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10000, <1/1000); very rare (<1/10000); unknown frequency (cannot be determined from the available data).
From the heart: commonly - increased heartbeat, bradycardia.
From the nervous system: uncommon - dizziness, headache, drowsiness (at high doses).
From the respiratory system, chest, and mediastinum: uncommon - increased bronchial secretion, bronchospasm.
From the gastrointestinal tract: commonly - increased salivation, nausea; uncommon - vomiting at high doses; rare - diarrhea, epigastric pain.

From the liver: unknown frequency - jaundice.
From the skin and subcutaneous tissue: commonly - increased sweating; uncommon - allergic reactions, including rash, itching, hives, angioneurotic edema.
From the reproductive system: increased uterine tone.
From the musculoskeletal and connective tissue: uncommon - muscle spasms (at high doses).
From the immune system: unknown frequency - hypersensitivity reactions (including allergic dermatitis, anaphylactic shock, asthma, toxic epidermal necrolysis, erythema, hives, wheezing, laryngeal edema, injection site rash).
General disorders and administration site conditions: uncommon - weakness (at high doses).

Anticholinergic agents, such as atropine, can reduce salivation and bradycardia.
In case of adverse side effects, the dose should be reduced or the use of the medicinal product temporarily discontinued for 1–2 days.

Incompatibility:
The medicinal product should not be mixed with other solutions, except those indicated in the "Method of administration and doses" section.

Shelf life:
2 years.

Storage conditions:
Store in the original package at a temperature not exceeding 25°C (77°F). Do not freeze.
Keep out of reach of children.

Packaging:
1 ml of solution in ampoules, 5 ampoules per blister pack. 2 blister packs (10 ampoules) in a cardboard box.

Dispensing category:
Prescription only.

Manufacturer: PrJSC "Lekhim-Kharkiv".

Location of the manufacturer and address of its activity:
Ukraine, 61115, Kharkiv region, Kharkiv, Severin Pototsky Street, Building 36.

Applicant: LLC "Pharmaceutical Company "Salutaris".

Applicant's location: Ukraine, 01042, Kyiv, Druzhby Narodiv Blvd., 9.

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