

TOLIMEX
Instructions
on medical use of the drug

Tradename: Tolimex.

International nonproprietary name: Tolperisone hydrochloride.

Dosage form: Solution for injection in ampoules.

Compound:

Active ingredients: 100 mg of tolperisone hydrochloride and 2.5 mg of lidocaine hydrochloride in each 1 ml ampoule;

Excipients: methyl parahydroxybenzoate, diethylene glycol monoethyl ether, water for injection.

Pharmacotherapeutic group: Centrally acting muscle relaxant.

Pharmacological properties:

Pharmacokinetics: Tolperisone hydrochloride undergoes intensive metabolism in the liver and kidneys. It is excreted by the kidneys, almost exclusively (> 99%) in the form of metabolites, the pharmacological activity of which is unknown.

Lidocaine hydrochloride: absorption - complete (the rate of absorption depends on the site of administration and dose). TC_{max} with intramuscular administration - 30-45 minutes. Communication with plasma proteins - 50-80%. Quickly distributed in tissues and organs. Penetrates the BBB and the placental barrier, secreted into breast milk (40% of the concentration in maternal plasma). Metabolized in the liver (90-95%) with the participation of microsomal enzymes by dealkylation of the amino group and cleavage of the amide bond with the formation of active metabolites. Excreted with bile (part of the dose is reabsorbed in the gastrointestinal tract) and kidneys (up to 10% unchanged).

Pharmacodynamics:

muscle relaxant. The mechanism of action is not fully understood. It has a membrane-stabilizing, local anesthetic effect, inhibits the conduction of impulses in primary afferent fibers and motor neurons, which leads to blocking of spinal mono- and polysynaptic reflexes. It also probably secondarily inhibits the release of mediators by inhibiting the entry of Ca^{2+} into synapses. In the brain stem, it eliminates the facilitation of excitation along the reticulospinal tract. Increases peripheral blood flow regardless of the influence of the central nervous system. The weak antispasmodic and adrenergic blocking effect of tolperisone plays a role in the development of this effect.

Indications for use:

- Treatment of pathologically increased tone and spasms of striated muscles resulting from organic lesions of the central nervous system (damage to the pyramidal tracts, multiple sclerosis, cerebral stroke, myelopathy, encephalomyelitis, etc.);
- Moderate to severe myofascial pain syndrome (including muscle spasms in dorsopathies), treatment of increased tone and muscle spasms, muscle contractures accompanying diseases of the movement organs (for example, spondylosis, spondyloarthritis, cervical and lumbar syndromes, arthrosis of large joints);
- Rehabilitation treatment after orthopedic and traumatological operations;
- As part of combination therapy for obliterating vascular diseases (obliterating atherosclerosis, diabetic angiopathy, thromboangiitis obliterans, Raynaud's disease, diffuse scleroderma), diseases arising from a disorder of vascular innervation (acrocyanosis, intermittent angioedema);
- Little's disease (CP) and other encephalopathies accompanied by muscular dystonia;
- Postthrombotic disorders of lymph circulation and venous circulation;
- Extrapyrarnidal disorders (postencephalitic and atherosclerotic parkinsonism);
- Treatment of painful muscle spasms.

Contraindications for use:

Hypersensitivity to any of the components of the drug (including lidocaine), myasthenia gravis, children under 18 years of age, pregnancy, lactation (due to lack of data).

with caution in patients with renal and hepatic insufficiency. No dose adjustment is required.

Side effects:

Muscle weakness, headache, hypotension, nausea, vomiting, abdominal discomfort.

Rarely: allergic reactions (skin rash, including erythematous, urticaria, itching, angioedema, anaphylactic shock, shortness of breath).

Drug interactions:

data on interactions with drugs that limit the use of Tolimex.

It is possible to use the drug in combination with sedatives, hypnotics and drugs containing ethanol. Does not enhance the effect of ethanol on the central nervous system.

It enhances the effect of non-steroidal anti-inflammatory drugs (NSAIDs), so when administered concomitantly, a reduction in the dose of NSAIDs may be required.

Directions for use and dosage:

Adults daily: 1 ml 2 times a day, intramuscularly or 1 ml 1 time a day intramuscularly. The course of treatment is selected individually by the doctor.

Overdose:

Symptoms: ataxia, tonic and clonic convulsions, dyspnea and respiratory arrest.

Treatment: there is no specific antidote; in case of overdose, symptomatic and supportive treatment is recommended.

Precautionary measures:

Impact on the ability to drive vehicles and operate machinery:

Care must be taken when driving vehicles and other potentially dangerous activities that require increased concentration and speed of psychomotor reactions.

Release form:

P solution for injection in ampoules of 1 ml, 5 ampoules in a package.

Storage conditions:

Store at a temperature not exceeding 25 °C.

Conditions for dispensing from pharmacies:

By doctor's prescription.

Made for:

MAXX PHARM LTD.

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