TOLIMEX
Instructions
on medical use of the drug

Tradename: Tolimex.
International nonproprietary name: Tolperisone hydrochloride.
Composition: *Each 1 tablet contains:*
Active ingredient: tolperisone hydrochloride 150 mg;
Excipients: citric acid monohydrate 0.730 mg and 2.190 mg; colloidal silicon dioxide 0.800 mg and 2.400 mg; stearic acid 1,700 mg and 5,100 mg; talc 4,500 mg and 13,500 mg; microcrystalline cellulose 14,000 mg and 42,000 mg; corn starch 29.770 mg and 89.310 mg; lactose monohydrate 48,500 mg and 145,500 mg;
Description of the dosage form:
White or almost white film-coated tablets are round, biconvex, with a weak characteristic odor, white or almost white tablets on the break.
Pharmacotherapeutic group: Centrally acting muscle relaxant.
Pharmacological properties:
Pharmacokinetics:
After administration, tolperisone is well absorbed from the gastrointestinal tract. The maximum concentration is reached after 0.5-1 hour, bioavailability is about 20%.
Tolperisone is metabolized in the liver and kidneys. Excreted in urine in the form of metabolites (more than 99%).
The pharmacological activity of the metabolites is unknown.
Pharmacodynamics:
Centrally acting 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, spondyloarthrosis, 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,
- Extrapyramidal disorders (postencephalitic and atherosclerotic parkinsonism);
- Treatment of painful muscle spasms.

Contraindications for use:

- hypersensitivity to any of the components of the drug;
- myasthenia gravis;
- pregnancy and lactation;
- children up to 3 years old.

Pregnancy and lactation: Due to the lack of data on use during pregnancy and breastfeeding, the use of Tolimex during these periods is not recommended.

Side effects:
Muscle weakness, headache, hypotension, nausea, vomiting, abdominal discomfort. When the dose is reduced, side effects usually go away.
In rare cases, allergic reactions occur (skin itching, erythema, urticaria, angioedema, anaphylactic shock, bronchospasm).
Drug interactions:
data on interactions 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.
Tolperisone enhances the effect of niflumic acid; when using these drugs simultaneously, it may be necessary to reduce the dose of niflumic acid.
General anesthesia, peripheral muscle relaxants, psychotropic drugs, clonidine - enhance the effect of tolperisone.
Mode of application:
Take orally after eating, without chewing, with a small amount of water.
Adults and children over 14 years of age: at the beginning of treatment, 50 mg is prescribed 2-3 times a day in the first days of therapy, then 150 mg up to three times a day - if the drug is well tolerated in the subsequent period. The recommended daily dose, depending on the individual need and tolerability of the drug by the patient, is 150-450 mg, divided into 3 doses.
Children from 6 to 14 years old: daily 2-4 mg/kg body weight, in three divided doses.
Children from 3 to 6 years old: prescribed orally in a daily dose of 5 mg/kg body weight, divided into 3 doses.

Overdose:
reports of overdose with Tolimex.
There is no specific antidote; in case of drug overdose, gastric lavage and symptomatic therapy are recommended.
Precautionary measures
Use strictly as prescribed by your doctor to avoid complications!
Impact on the ability to drive vehicles and operate machinery:
No studies have been conducted, but no such information has been reported over many years of use of the drug.
Release form:
Tablets 150 mg for oral administration, No 30 per package.
Storage conditions:
Store at a temperature not exceeding 25 °C.
Conditions for dispensing from pharmacies:
On prescription.

Made for:
MAXX PHARM LTD
London, Great Britain