MAXXIFEN
Instructions
on medical use of the drug

Trade name of the drug: Maxxifen.

MNN: Ibuprofen.

Dosage form: With suspensia for oral administration.

Pharmaco-therapeutic group: Non-steroidal anti-inflammatory drugs. Painkillers and anti-inflammatory drugs.

Composition: *Every 5 ml of suspension contains:*

Ibuprofen 100 mg.

Pharmachologic effect:

Pharmacodynamics:

Maxxifen contains ibuprofen, which has antipyretic, analgesic and anti-inflammatory properties. Ibuprofen belongs to the group of non-steroidal anti-inflammatory drugs; the mechanism of action of ibuprofen, a derivative of propionic acid from the NSAID group, is due to inhibition of the synthesis of prostaglandins - mediators of pain, inflammation and hyperthermic reaction. Non-selectively blocks COX-1 and COX-2, as a result of which it inhibits the synthesis of prostaglandins. Reversibly inhibits platelet aggregation. It has analgesic, antipyretic and anti-inflammatory effects. The analgesic effect is most pronounced for inflammatory pain. The effect of the drug lasts up to 8 hours.

Pharmacokinetics:

Absorption – high, quickly and almost completely absorbed from the gastrointestinal tract (binding with blood plasma proteins – 90%). After taking the drug on an empty stomach, it is detected in the blood plasma after 15 minutes, Cmax $_{of}$ ibuprofen in the blood plasma is achieved after 60 minutes. Taking the drug with food may increase TC $_{max}$ up to 1-2 hours. T $_{1/2\ -}$ 2 hours. Slowly penetrates into the joint cavity, lingers in the synovial fluid, creating higher concentrations in it than in the blood plasma. Metabolized in the liver. It is excreted by the kidneys (no more than 1% unchanged) and, to a lesser extent, with bile.

Indications for use:

- for symptomatic treatment as an antipyretic for acute respiratory diseases (including influenza), childhood infections, other infectious and inflammatory diseases and post-vaccination reactions accompanied by an increase in body temperature;
- as a symptomatic analgesic for pain of mild or moderate intensity, including: toothache, headache, migraine, neuralgia, ear pain, sore throat, sprain pain, muscle pain, rheumatic pain, joint pain.

Mode of application:
For oral administration. Patients with hypersensitivity of the stomach to taking NSAIDs are recommended to take the drug with meals. The duration of treatment is no more than 3 days as an antipyretic and no more than 5 days as an analgesic. Between taking the drug, you should maintain a minimum 6-8 hour interval (or at least a 4 hour interval if necessary). Shake the bottle vigorously before use. The duration of treatment is determined by the doctor depending on the therapeutic effect and the nature of the disease. If the fever persists, you should consult a doctor.

Recommended use:

Children aged 3-6 months: 2.5 ml up to 3 times a day;

Children aged 6-12 months: 2.5 ml up to 3-4 times a day;

Children aged 1-3 years: 5.0 ml up to 3 times a day;

Children aged 4-6 years: 7.5 ml up to 3 times a day;

Children aged 7-9 years: 10 ml up to 3 times a day;

Children aged 10-12 years: 15 ml up to 3 times a day.

Post-immunization fever: Children under 6 months of age: 2.5 ml (50 mg) of the drug. If necessary, another 2.5 ml (50 mg) after 6 hours. Do not use more than 5 ml (100 mg) within 24 hours.

Side effects

When using the drug, patients may develop the following undesirable effects caused by ibuprofen:
From the digestive tract: pain in the epigastric and abdominal region, nausea, vomiting, flatulence, stool disorders, dyspepsia. In isolated cases, the development of gastrointestinal bleeding, ulcerative lesions and perforation of the digestive tract, heartburn, gastritis, stomatitis, jaundice, esophagitis and hepatitis was noted.
From the nervous system: headache, irritability, tinnitus, depression, sleep disturbances, psychomotor agitation, convulsions. In isolated cases, mainly in patients with autoimmune diseases, the development of aseptic meningitis was noted.
From the urinary system: papilonecrosis, increased plasma urea levels, decreased urea secretion, acute renal failure. In isolated cases, interstitial nephritis and nephrotic syndrome developed.
From the blood system: decreased hematocrit and hemoglobin, eosinophilia, thrombocytopenia, anemia, neutropenia, leukopenia, pancytopenia and agranulocytosis.
Allergic reactions: urticaria, exfoliative and bullous dermatitis, Quincke's edema, anaphylactic shock, bronchospasm, photosensitivity.
Other: alopecia, arterial hypertension or hypotension, edema, heart failure, palpitations, decreased visual acuity and changes in color perception. In addition, it is possible to develop dry mouth mucous membranes, decreased appetite and hearing impairment.
If side effects develop, you should consult a doctor. The risk of developing side effects of ibuprofen increases with prolonged therapy, reducing the intervals between single doses, and also if the recommended doses of the drug are exceeded.

Contraindications:

Maxxifen is not prescribed to patients with known intolerance to ibuprofen, additional components of the suspension, as well as other medicinal substances of the group of non-steroidal anti-inflammatory drugs (including patients with a history of the " aspirin triad"). **Maxxifen** should not be prescribed to patients with gastric ulcers and gastrointestinal bleeding (currently or in history), as well as impaired renal, liver and heart function.

In pediatric practice, the drug **Maxxifen** in the form of a suspension is used only for the treatment of children older than 3 months with a body weight of more than 5 kg.
Caution should be exercised when prescribing **Maxxifen** to patients with heart failure, fluid retention, arterial hypertension, a tendency to bronchospasm, autoimmune diseases, Crohn's disease and chronic colitis.
Maxxifen should be used with caution in patients receiving medications that increase the risk of developing gastric ulcers and gastrointestinal bleeding.
Maxxifen is used to treat children and adolescents under 12 years of age.

Drug interactions:

Maxxifen should not be prescribed in combination with other non-steroidal anti-inflammatory drugs. When using different forms of ibuprofen, the maximum daily dose and single dose are calculated taking into account all forms obtained.
Maxxifen for children may potentiate the effect of anticoagulants such as warfarin .
Antihypertensives, diuretics, tacrolimus and cyclosporines increase the risk of ibuprofen nephrotoxicity . Corticosteroids when used simultaneously with **Maxxifen** increase the risk of side effects from the digestive tract.
Ibuprofen may reduce plasma levels of cardiac glycosides.
When combined with ibuprofen and antiplatelet agents and selective serotonin inhibitors, the risk of gastrointestinal bleeding increases.
Ibuprofen may increase plasma concentrations of lithium and methotrexate .
The combined use of ibuprofen with mifepristone is prohibited .
The risk of developing hemarthrosis and hematoma increases with the combined use of zidovudine and ibuprofen.
The risk of developing seizures increases when taking ibuprofen and quinolone antibiotics simultaneously.

Overdose:

Maxxifen are significantly exceeded, patients may develop vomiting, pain in the epigastric region, stool disorders, headache, tinnitus, and gastrointestinal bleeding. With a further increase in dose, drowsiness or agitation, disorientation, convulsions, coma and metabolic acidosis may develop. In addition, in case of severe overdose, the development of renal failure and hepatotoxicity of ibuprofen is possible.

There is no specific antidote. In case of an overdose of **Maxxifen** suspension, gastric lavage is performed and enterosorbent agents are prescribed. In addition, in case of an overdose of ibuprofen, monitoring the patient's condition and prescribing supportive and symptomatic therapy are indicated.

Release form:

Maxifen suspension 100 ml in a bottle along with instructions for use in the package.

Storage conditions:

Store at a temperature not exceeding 25 °C, out of the reach of children.

The drug should not be used after the expiration date.

Vacation conditions:

On prescription.

Made for:
MAXX PHARM LTD.
London, Great Britain