Fenamax
Instructions
on medical use of the drug

Trade name: Fenamax.
MNN: Meloxicam.
Dosage form: Solution for intramuscular injection.
Composition: *1 ampoule contains:*
Active substance: meloxicam 15 mg;
Excipients: meglumine, glycofurol, poloxamer 188, glycine, sodium chloride, sodium hydroxide, water for injection.
Description:
Light yellow transparent liquid.
Pharmacotherapeutic group: NSAIDs.
Pharmachologic effect:
Pharmacodynamics:
Meloxicam is a derivative of enolic acid and belongs to the group of non-steroidal anti-inflammatory drugs, has a pronounced anti-inflammatory, analgesic and antipyretic effect. It exhibits high anti-inflammatory activity in all standard models of inflammation. The mechanism of action is due to the ability to inhibit the biosynthesis of prostaglandins - mediators of inflammation due to the selective inhibition of COX-2, providing a safer mechanism of action due to the selective inhibition of COX-2 compared to COX-1. The therapeutic effect of NSAIDs is associated with inhibition of the synthesis of COX-2, in while inhibition of COX-1 results in gastric and renal side effects.
The selectivity of COX-2 inhibition by meloxicam has been confirmed as in vitro and ex vivo. Meloxicam does not affect platelet aggregation and bleeding time when used in recommended doses ex vivo, in contrast to indomethacin, diclofenac, ibuprofen and naproxen, which significantly inhibit platelet aggregation and increase bleeding time.
When using meloxicam in recommended doses, a low incidence of gastrointestinal side effects (perforation, ulceration and bleeding) was found compared with standard doses of other NSAIDs.
Pharmacokinetics:
Meloxicam is almost completely absorbed when administered intramuscularly. Plasma concentrations of meloxicam are proportional to the administered dose. 60 minutes after intramuscular administration of 15 mg meloxicam , the maximum plasma concentration is approximately 1.62 mg/l.
Meloxicam binds very well to plasma proteins, especially albumin (90-100 %). Penetrates into synovial fluid, the concentration in synovial fluid is approximately 50% of the concentration in plasma. The volume of distribution is low, averaging 11 L.
Meloxicam is almost completely metabolized in the liver to form 4 pharmacologically inactive derivatives. The main metabolite, 5'- carboxymeloxicam (60% of the dose), is formed by oxidation of an intermediate metabolite, 5'-hydroxymethylmeloxicam, which is also excreted , but to a lesser extent (9% of the dose).
Meloxicam is excreted equally in feces and urine, mainly in the form of metabolites. In unchanged form, less than 5% of the daily dose is excreted in feces; in urine, unchanged, the drug is found only in trace amounts.
The average half-life of meloxicam is 20 hours. Plasma clearance averages 8 ml/min.
In elderly patients, plasma clearance is slightly lower.
Indications for use:
The drug is intended for symptomatic therapy, reducing pain and inflammation at the time of use, and does not affect the progression of the disease. Applicable for:
- rheumatoid arthritis;
- osteoarthritis;
- ankylosing spondylitis (Bechterew's disease);
- rheumatism of soft tissues;
- acute attack of gout;
- rheumatic inflammations;
- degenerative joint diseases accompanied by pain;
- painful conditions after operations, injuries, dental interventions.

Contraindications:
- a history of hypersensitivity to meloxicam or other NSAIDs, or to the auxiliary components of the drug;
- complete or incomplete combination of bronchial asthma, recurrent polyposis of the nose and paranasal sinuses and intolerance to acetylsalicylic acid or other NSAIDs (including a history);
- condition after coronary artery bypass surgery;
- decompensated heart failure;
- erosive and ulcerative changes in the mucous membrane of the stomach or duodenum, active gastrointestinal bleeding;
- inflammatory bowel diseases (ulcerative colitis, Crohn's disease);
- cerebrovascular bleeding or other bleeding;
- severe liver failure or active liver disease;
- chronic renal failure;
- pregnancy, lactation period;
- ongoing anticoagulant therapy;
- age up to 18 years.

Directions for use and dosage:
Fenamax is prescribed to adult patients. Intramuscular administration of the drug is indicated for 3 days.
The drug is administered via deep intramuscular injection.

The drug cannot be administered intravenously.
Fenamax ampoules should not be mixed in the same syringe with other medications.
The maximum recommended dose is 15 mg 1 time per day.
In patients with an increased risk of side effects, treatment begins with a dose of 7.5 mg.

Side effect:

From the gastrointestinal tract: dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhea (>1%); transient changes in liver function indicators (including increased levels of transaminases or bilirubin), belching, esophagitis, ulcerative lesions of the gastrointestinal tract, hidden or macroscopically visible gastrointestinal bleeding (0.1 - 1.0%); colitis (<0.1%).
From the hematopoietic system: anemia (> 1.0%); leukopenia, changes in the leukocyte formula, thrombocytopenia (0.1 - 1.0%).
From the skin: itching, skin rash (> 1.0%), urticaria (0.1 - 1.0%); photosensitivity (<0.1%). In rare cases, it is possible to develop bullous reactions, erythema multiforme , Stevens -Johnson syndrome, toxic epidermal necrolysis .
From the respiratory system: acute attacks of bronchial asthma (<0.1%).
From the nervous system: headache (> 1.0%); dizziness, tinnitus, drowsiness (0.1 - 1.0%); confusion, disorientation, mood changes (<0.1%).
From the cardiovascular system: edema (> 1.0%); increased blood pressure, palpitations, hot flashes (0.1 - 1.0%).
From the urinary system: changes in laboratory indicators of renal function (increased levels of creatinine and/or urea in the blood) (0.1 - 1.0%); acute renal failure (<0.1%).
Allergic reactions: angioedema, immediate hypersensitivity reactions (including anaphylactic and anaphylactoid) (<0.1%).
Local reactions: swelling at the injection site (>1%); pain at the injection site (<1%).

Overdose:

There is no known antidote; in case of overdose with Fenamax, symptomatic and supportive treatment should be carried out.

Interaction with other drugs:

Other NSAIDs, incl. salicylates (acetylsalicylic acid): simultaneous use of more than one NSAID increases the risk of gastrointestinal ulceration and gastrointestinal bleeding due to synergistic action. The combined use of meloxicam and other NSAIDs is not recommended.
Anticoagulants, antiplatelet agents , systemic heparin, thrombolytic agents: increase the risk of bleeding. If it is impossible to avoid the simultaneous use of these drugs, careful monitoring of the effect of anticoagulants is necessary.
Lithium: NSAIDs increase plasma lithium concentrations by decreasing renal excretion of lithium. The combined use of lithium and NSAIDs is not recommended. If such combination therapy is necessary, the concentration of lithium in plasma should be monitored at the beginning of treatment, when selecting the dose and when discontinuing meloxicam.
Methotrexate: NSAIDs may decrease the tubular secretion of methotrexate and thus increase the plasma concentration of methotrexate. If combination therapy is necessary, blood count and renal function should be monitored. Caution must be exercised if NSAIDs and methotrexate are used simultaneously for 3 days, because The concentration of methotrexate in plasma may increase and, as a result, toxic effects may occur.
Cyclosporine: NSAIDs, by acting on renal prostaglandins, may increase nephrotoxicity cyclosporine. In case of combination therapy, renal function should be monitored.
Intrauterine contraceptives: NSAIDs reduce the effectiveness of intrauterine contraceptives.
Diuretics: The use of NSAIDs increases the risk of acute renal failure in patients with dehydration. Patients taking meloxicam and diuretics simultaneously should receive sufficient fluids. Before starting treatment, a kidney function test is necessary.
Antihypertensive agents (eg, beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, vasodilators, diuretics). NSAIDs reduce the effect of antihypertensive drugs due to inhibition of prostaglandins, which have vasodilating properties.
Cholestyramine: increases the excretion of meloxicam due to its binding in the gastrointestinal tract.

Features of application:

The use of Fenamax , like other NSAIDs, requires strict monitoring of patients with a history of gastrointestinal diseases, as well as patients taking anticoagulants. If you have a peptic ulcer or gastrointestinal bleeding, Fenamax is contraindicated.
As with other NSAIDs, potentially fatal gastrointestinal complications (gastrointestinal bleeding, ulceration, or perforation) may occur at any time during treatment with or without a history of serious gastrointestinal disease.
NSAIDs inhibit the synthesis of renal prostaglandins, which are necessary to maintain renal blood flow. In patients with reduced renal blood flow, the use of NSAIDs may cause renal failure, which disappears after discontinuation of the drug. In patients with mild or moderately severe renal impairment, the dose of the drug may not be reduced, but careful monitoring of renal function is necessary.
In some rare cases, NSAIDs can lead to the development of interstitial nephritis, glomerulonephritis , renal medullary necrosis or the development of nephrotic syndrome. Patients with chronic renal failure, after extensive surgical operations (which caused hypovolemia), as well as patients with cirrhosis of the liver are prone to such complications. In this case, monitoring of diuresis and renal function is necessary from the very beginning of therapy.
NSAIDs, when taken together with diuretics, can increase the retention of sodium, potassium and water in the body and affect the natriuretic effect of diuretics, as a result of which, in predisposed patients, heart failure or arterial hypertension may occur or worsen.
The drug is prescribed with caution to weakened patients, elderly people, and patients with heart failure.
Meloxicam, like any other NSAID, can mask the symptoms of an underlying infectious disease.
NSAIDs may increase the risk of cardiovascular thrombosis, myocardial infarction and cerebrovascular accidents, including death. The risk increases with increasing duration of drug use. Patients with cardiovascular disease or who have factors predisposing them to the development of cardiovascular disease are at greater risk .
Like other drugs that inhibit COX synthesis, meloxicam can harm the fertilization process and is therefore not recommended for women who are planning to become pregnant.

Effect on the ability to drive a car or operate machinery:

Patients with visual impairments, patients experiencing drowsiness or other disorders of the central nervous system should refrain from driving or using machinery.

Release form:
Solution for injection in 1.5 ml clear glass ampoules. The thermoplastic separator contains 3 ampoules in a cardboard box along with an insert.
Storage conditions:
Store at a temperature not exceeding 25 ºC in a place protected from light.
Keep out of the reach of children.
Best before date:
3 years from the date of production.
Do not use after the expiration date.
Conditions for dispensing from pharmacies:
Dispensed by prescription.

Made for:
MAXX PHARM LTD
London, Great Britain