MOBICORT
Instructions
on medical use of the drug

Trade name of the drug: Mobicort.
International nonproprietary name:
Meloxicam + Cyanocobalamin + Betamethasone.
Dosage form: Enteric-coated tablets.
Compound: *Each enteric-coated tablet contains:*
Meloxicam USP …… …….15 mg;
Cyanocobalamin USP …….2.5 mg;
Betamethasone sodium phosphate USP ……0.30 mg.
Pharmaco-therapeutic group: Non-steroidal anti-inflammatory drugs. Meloxicam in combination. NSAIDs, B vitamins, GCS.
ATX code: M 01 AB 55.

Pharmacological properties:
Pharmacodynamics:
Meloxicam - the mechanism of action is associated with inhibition of prostaglandin synthesis as a result of selective suppression of the enzymatic activity of COX-2, which is involved in the biosynthesis of prostaglandins in the area of inflammation. When used in high doses, long-term use and individual characteristics of the organism, COX-2 selectivity decreases. Suppresses the synthesis of prostaglandins in the area of inflammation to a greater extent than in the gastric mucosa or kidneys, which is associated with relatively selective inhibition of COX-2. Less commonly causes erosive and ulcerative changes in the gastrointestinal tract. To a lesser extent, meloxicam acts on COX-1, which is involved in the synthesis of prostaglandins that protect the gastrointestinal mucosa and take part in the regulation of blood flow in the kidneys.
Cyanocobalamin - the dose of vitamin in the drug Mobicort is regarded as therapeutic and is optimally suited for effective use in urgent care in neurology. It is in high doses that the pronounced analgesic effect of vitamin B12 is manifested, and acute pain syndrome is quickly relieved. When high doses of vitamin B12 are used, its ability to activate myelin resynthesis, including resynthesis in the affected areas of nerves, is manifested. Such doses in some cases make it possible to restore the synthesis of myelin during its increased decay, during inflammatory rheumatic processes. Vitamin B12, supplied as cyanocobalamin, acts through its coenzymes in many metabolic processes, including the synthesis of myelin, an essential lipoprotein for the integrity of the nervous and peripheral system.
Betamethasone is a synthetic corticosteroid. When used systemically, the therapeutic activity of betamethasone is due to anti-inflammatory, antiallergic, immunosuppressive and antiproliferative effects. Its anti-inflammatory activity exceeds the level of hydrocortisone activity by 30 times, and does not have mineralocorticoid activity.
When introduced into the body by injection or orally, it binds to DNA, causing gene induction and blocking, ultimately leading to its anti-inflammatory, immunosuppressive effect.
Pharmacokinetics:
Meloxicam - binding to plasma proteins - 99%. Passes through the BBB, penetrates into the synovial fluid. Concentration in synovial fluid is 50% of plasma concentration. Metabolized in the liver to inactive metabolites. T1/2 - 20 hours. Plasma clearance - on average 8 ml/min (decreases in old age). Excreted through the intestines and kidneys (in approximately equal proportions), unchanged (through the intestines) - 5% of the daily dose.
Vitamin B12 - connection with plasma proteins - 90%. The maximum concentration after intramuscular administration is after 1 hour. The half-life is 500 days. Excreted from the liver with bile into the intestines and reabsorbed into the blood
Betamethasone - binding to plasma proteins is about 64%, Vd - 84 l. Metabolized in the liver. Metabolites are excreted mainly by the kidneys, a small part - with bile. Systemic absorption after external use is 12-14%.
Indications for use:
MOBICORT is used for symptomatic treatment of:
• rheumatoid arthritis;
• inflammatory and degenerative diseases of the musculoskeletal system, such as arthropathy, dorsopathies (for example, sciatica, lumboischialgia, cervical brachialgia , brachial periarthritis, Reiter's syndrome, ankylosing spondylitis (Bechterew's disease), acute tenosynovitis), accompanied by pain;
• symptomatic treatment of osteoarthritis (arthrosis, degenerative joint diseases), incl . with a pain component.
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. Parenterally used as initial therapy and short-term symptomatic treatment.
Directions for use and dosage:
The drug is used intramuscularly (ampoules) and orally (tablets). The dosage regimen is set individually, depending on the intensity of pain and the severity of the inflammatory process. The drug should not be used simultaneously with other NSAIDs. The total daily dose of the drug, used in the form of different dosage forms, should not exceed the dose (7.5 mg-15 mg for meloxicam , respectively) depending on the intensity of pain and the severity of the inflammatory process. IM administration of the drug is indicated only during the first 2-3 days of therapy. Subsequently, treatment is continued with the use of oral dosage forms.
Inside: Tablets are recommended to be taken 1 tablet 1 time per day, with meals. The tablet must be taken with water. The course of treatment is determined by the attending physician depending on the severity of the symptoms of the disease.
Side effects:
From the gastrointestinal tract: nausea, vomiting, anorexia, flatulence, constipation, diarrhea, acute drug-induced erosions and gastrointestinal ulcers, gastrointestinal bleeding.
From the nervous system: convulsions, increased intracranial pressure with papilledema (usually after completion of treatment), dizziness, headache, drowsiness, irritability.
From the liver: sometimes - increased transaminases or rarely - hepatitis with / without jaundice.
From the skin: sometimes - erythema and skin rashes, dermatitis, rashes, angioedema. Rarely - urticaria. Isolated cases of Stevens -Johnson syndrome, exudative polymorphic erythema and toxic epidermolysis. Deterioration of wound healing, thinning of the skin, petechiae and ecchymosis, facial erythema. Upon administration, there is a burning sensation and the formation of an infiltrate.
From the kidneys: isolated cases of acute renal failure, hematuria and proteinuria, oliguria, interstitial nephritis, papillary necrosis, azotemia.
From the circulatory system: isolated cases of leukopenia, hemolytic anemia and agranulocytosis.
From the cardiovascular system: arterial hypertension, congestive heart failure and rapid heartbeat.
From the side of water and electrolyte balance: sodium retention, increased potassium excretion and hypokalemic alkalosis.
From the musculoskeletal system: muscle weakness, myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of the femoral head and / or pathological fractures of long bones, tendon ruptures, joint instability (after repeated injections).
From the endocrine system: menstrual irregularities, adrenal insufficiency, especially when a stressful situation occurs (after injuries, surgical interventions, systemic diseases).
Psychoneurological disorders: euphoria, mood changes, depression (with severe psychotic reactions), increased irritability, insomnia.
From the senses: posterior subcapsular cataract, increased intraocular pressure, glaucoma, exophthalmos and tinnitus.
Metabolic disorders: negative nitrogen balance due to protein catabolism.
Other: bronchospasm , systemic anaphylactic reactions. Clinical trial and epidemiological data indicate an increased risk of thrombotic complications (eg, myocardial infarction or stroke) associated with the use of meloxicam, particularly at high therapeutic doses (150 mg per day) and with long-term use.

Contraindications:

- hypersensitivity to the components of the drug or other NSAIDs;
- a history of bleeding or perforation of the gastrointestinal tract associated with previous treatment with nonsteroidal anti-inflammatory drugs (NSAIDs);
- active peptic ulcer/bleeding or history of recurrent peptic ulcer/bleeding (two or more separate episodes of established ulcer or bleeding);
- severe renal and liver failure;
- decompensated heart failure;
- severe form of hypertension;
- systemic mycosis;
- active tuberculosis;
- osteoporosis;
- Cushing syndrome;
- diabetes;
- hepatitis A, B and other viral infections;
- immunodeficiency conditions (including AIDS or HIV infection);
- vaccination period;
- during pregnancy and breastfeeding
- intramuscular administration to patients with idiopathic thrombocytopenic purpura;
- gout;
- treatment with systemic coagulants;
- children under 18 years of age;
- congestive heart failure;
- coronary heart disease in patients with angina pectoris who have had myocardial infarction;
- cerebrovascular diseases in patients who have suffered a stroke or have episodes of transient ischemic attacks;
- peripheral arterial diseases;
- treatment of perioperative pain during coronary artery bypass grafting (or use of a heart-lung machine).

Overdose:
Symptoms: There is no typical clinical picture of an overdose of the drug. Overdose may cause symptoms such as vomiting, intestinal bleeding, diarrhea, dizziness, ringing in the ears or seizures. In case of severe poisoning, acute renal failure and liver damage are possible.
Treatment: Treatment of acute NSAID poisoning consists primarily of supportive measures and symptomatic treatment. Forced diuresis, dialysis or hemoperfusion cannot guarantee the removal of non-steroidal anti-inflammatory drugs, due to their high binding to plasma proteins and intensive metabolism.
Symptoms of betamethasone overdose: Acute betamethasone overdose does not create a life-threatening situation. The administration of high doses of GCS for several days does not lead to undesirable consequences (except for cases of use of very high doses or in the case of use in diabetes mellitus, glaucoma, exacerbation of erosive and ulcerative lesions of the gastrointestinal tract or in patients simultaneously undergoing therapy with digitalis, diuretics, etc. remove potassium).
Treatment: careful medical monitoring of the patient's condition is necessary. It is necessary to maintain optimal fluid intake and monitor plasma and urinary electrolytes, paying particular attention to the balance of sodium and potassium in the body. If an imbalance of these ions is detected, appropriate therapy must be carried out.
Pregnancy and lactation:
Pregnancy:
The safe use of this medication during pregnancy has not been established. Therefore, its use requires that the potential benefits to the mother outweigh the risks to the fetus. Drugs known to inhibit prostaglandin synthesis and release (increase the incidence of premature closure of patent ductus arteriosus) are not recommended. Infants born to mothers who received corticosteroids during pregnancy should be closely monitored for signs of hypoadrenalism.
Lactation:
Corticosteroids appear in human milk and may suppress growth, interfere with endogenous corticosteroid production, or have other unwanted effects.
Release form:
Enteric-coated tablets 15 mg + 2.5 mg + 0.30 mg.
14 tablets per pack. 7 tablets in a blister. Two of these blisters are placed in a cardboard box along with a leaflet.
Storage conditions:
Store in a dry place, protected from light, at a temperature not exceeding 8 °C to 30 °C.
Keep the drug out of the reach of children.

Do not use the drug after the expiration date indicated on the blister and cardboard box.

Conditions for dispensing from pharmacies:
By doctor's prescription.

Made for:
MAXX PHARM LTD
London, Great Britain