MELOSPEY

Instructions for the medicinal product

Trade name: Melospey.
International Nonproprietary Name: Meloxicam.
Dosage form: Rectal suppositories.
Composition: each suppository contains:
Meloxicam BP 15 mg;
Excipients q.s.
Pharmacotherapeutic group: Non-Steroidal Anti-Inflammatory agent, Oxicams.
ATC Code: M01AC06.
Pharmacological properties:
Pharmacodynamics:
Meloxicam is an nonsteroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. Prostaglandins are substances that contribute to inflammation of joints. Meloxicam inhibits prostaglandin synthetase (cylooxygenase 1 and 2) and leads to a decrease of the synthesis of prostaglandins, therefore, inflammation is reduced.
Anti-inflammatory effects of meloxicam are believed to be due to inhibition of prostaglandin synthetase (cylooxygenase), leading to the inhibition of prostaglandin synthesis. As prostaglandins sensitize pain receptors, inhibition of their synthesis may be associated with the analgesic and antipyretic effects of meloxicam.
Pharmacokinetics:
At rectal using, meloxicam well absorbed into the systemic circulation, absolute bioavailability is 89%. Stable therapeutic concentration in the blood reaches in 3-5 days after starting the treatment. Protein binding 99.4% bound, primarily to albumin.
Meloxicam is almost completely metabolized into inactive metabolites by the cytochrome P450 (CYP450) isozymes. CYP2C9 is primarily responsible for metabolism of meloxicam while CYP3A4 plays a minor role. An intermediate metabolite, 5'-hydroxymethyl meloxicam, is further metabolized to 5'-carboxy meloxicam, the major metabolite. Peroxidase activity is thought to produce the two other inactive metabolites of meloxicam.
Meloxicam is almost completely metabolized to four pharmacologically inactive metabolites. Meloxicam excretion is predominantly in the form of metabolites, and occurs to equal extents in the urine and feces. Only traces of the unchanged parent compound are excreted in the urine (0.2%) and feces (1.6%). The extent of the urinary excretion was confirmed for unlabeled multiple 7.5 mg doses: 0.5%, 6% and 13% of the dose were found in urine in the form of meloxicam, and the 5'-hydroxymethyl and 5'-carboxy metabolites, respectively.
In the elderly observed only a slight increase in half-life of the drug and reduced plasma clearance (especially for women).
There was no significant change in the pharmacokinetics of meloxicam, and increased risk of side effects, at appointment of the drug to patients with hepatic or mild renal impairment (creatinine clearance 20-40 ml/min).
Indications for use:
_ Long-term symptomatic treatment of rheumatoid arthritis or ankylosing spondylitis.
Contra-indications:
_ Hypersensitivity to meloxicam or to one of the excipients or hypersensitivity to substances with a similar action, e.g. NSAIDs, aspirin.
_ Should not be given to patients who have developed signs of asthma, nasal polyps, angioneurotic edema or urticaria following the administration of aspirin or other NSAIDs.
_ History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
_ Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
_ Past history of proctitis and rectal bleeding.
_ Severely impaired liver function.
_ Non-dialysed severe renal failure;
_ Gastrointestinal bleeding, history of cerebrovascular bleeding or other bleeding disorders.
_ Severe heart failure.
_ Third trimester of pregnancy.
_ Children and adolescents aged under 16 years.
Dosage and Direction for use:
Rectal use.
Adults and adolescents over 16 years use 1 suppository once a day.
Melospey suppositories should be used for the shortest time possible (5-7 days), afterwards Meloxicam tablet should be used.
Do not exceed the recommended maximum dose of 15 mg a day.
Side-effects:
Gastro-intestinal tract: dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhea; rarely - esophagitis, stomatitis, eructation, erosive and ulcerative lesions of the gastrointestinal tract, macroscopically visible or hidden gastrointestinal bleeding, transient changes in the function liver (elevated liver transaminases or bilirubin); in some cases – perforation bowel, colitis.
Central and peripheral nervous system: headache; rarely - dizziness, noise in the ears, drowsiness; in some cases - mood changes, confusion, insomnia, nightmares.
Cardio-vascular system: edema; rarely - increased blood pressure, tachycardia.
Urinary system: rarely - changes in laboratory parameters of renal function (Increases creatinine level and/or urea in the blood); in some cases - acute renal failure.
Hematopoietic system: rarely - anemia, leukopenia and thrombocytopenia.
Dermatological reactions: itching, rash; rarely – urticaria; in some cases - photosensitivity, bullous reaction, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.
Allergic reactions: in some cases - angioedema, hypersensitivity reactions immediate type (including anaphylactic and anaphylactoid).
Other: the reactions of local irritation (burning, itching in the anorectal region), in some cases - conjunctivitis, visual disturbances (including blurred).
Overdose:
Symptoms: lethargy, drowsiness, nausea, vomiting, pain in epigastric area, possible gastrointestinal bleeding. Severe poisoning can result in arterial Hypertension, acute renal failure, liver dysfunction, coma, cardiac arrest.
Treatment: cancellation of the drug, rectal lavage, symptomatic therapy. No specific antidote.
Drug interactions:
Other NSAIDs, including high doses of salicylates: Administration of several NSAIDs together may increase the risk of ulcers and of gastrointestinal bleeding, via a synergistic effect.
Oral anticoagulants, heparin and ticlopidine: Increased risk of bleeding via inhibition of platelet function and damage to the gastroduodenal mucosa.
Careful monitoring of the effects of anticoagulants is thus essential if it proves impossible to avoid such combined prescription.
Lithium: NSAIDs increase blood lithium levels, which may then reach toxic values.
Methotrexate: NSAIDs may accentuate the haematologic toxicity of methotrexate.
Intrauterine contraceptive devices: NSAIDs appear to decrease the efficacy of intrauterine contraceptive devices.
Cautions:
In the event of peptic ulcer or gastrointestinal bleeding, development of side effects of the skin and mucous membranes, the drug should be discontinued. In patients with reduced blood volume and reduced glomerular filtration (dehydration, heart failure, liver cirrhosis, nephrotic syndrome, clinically expressed kidney disease, diuretics, dehydration after major surgical operations) may cause clinically significant renal failure, which is completely reversible after discontinuation of the drug (these patients in the early treatment should be monitored daily urine output and renal function).
With persistent and substantial increase in transaminases and other changes in liver function drug should be canceled and conduct control tests.
Visual disturbances, drowsiness, vertigo (dizziness) or other central nervous system disturbances may occur with this product. If affected do not drive or operate machinery.
Presentation:
5 Suppositories in a strip of Polyvinyl chloride / Polyethylene (PVC/PE) foil along with leaflet.
Storage:
Keep in dry place, protected from light at a temperature not below 30°C. Keep out of reach of children.
Shelf life:
3 years. Do not use after the expiry date.
Distribution Condition:
Prescription only medicine (POM).

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SPEY

Manufactured for:
SPEY MEDICAL PVT. LTD.
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Floor, Greater Kailash-I,
New Delhi-110048,
Delhi, India.

Manufactured by:
BLISS GVS PHARMA LIMITED
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Maharashtra State, India.