



Melcam[®]

Meloxicam
Analgesic & Anti-inflammatory

COMPOSITION

Melcam[®] 7.5 Tablet : Each tablet contains Meloxicam BP 7.5 mg.

Melcam[®] 15 Tablet : Each tablet contains Meloxicam BP 15 mg.

Melcam[®] 7.5 Suppository : Each suppository contains Meloxicam BP 7.5 mg.

Melcam[®] 15 Suppository : Each suppository contains Meloxicam BP 15 mg.

PHARMACOLOGY

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam family, with anti-inflammatory, analgesic and antipyretic properties. The bioavailability of Meloxicam following oral administration is 89% on the average. With the doses of 7.5 mg & 15 mg plasma concentrations are proportional to dose: 0.4 to 1.0 mg/litre for 7.5 mg & 0.8 to 2.0 mg/litre for 15 mg, on an average. Meloxicam is very strongly bound to plasma proteins, essentially albumin (99%). Meloxicam is extensively metabolised, chiefly by oxidation of the methyl radical attached to the thiazolyl ring. Elimination in unchanged form accounts for 3% of the dose. Half of the substance is eliminated in urine & the other half in the faeces. The mean elimination half life is 20 hours.

INDICATION

- Osteoarthritis.
- Rheumatoid arthritis.
- Ankylosing spondylitis.

DOSAGE AND ADMINISTRATION

For Adults:

Osteoarthritis: 7.5 mg/day. If necessary, in the absence of improvement, the dose may be increased to 15 mg/day.

Rheumatoid arthritis: 15 mg/day. In elderly patients the recommended dose for long term treatment is 7.5 mg/day.

Ankylosing spondylitis: 15 mg/day. In elderly patients the recommended dose is 7.5 mg/day.

Do not exceed the dose of 15 mg/day. The total daily amount should be taken as a single dose. Patients with increased risks for adverse reactions should start treatment with 7.5 mg/day. In dialysis patients with severe renal failure the dose should not exceed 7.5 mg/day.

For Children:

The pharmacokinetics of Meloxicam in paediatric patients under 18 years of age have not been investigated.

CONTRAINDICATION AND PRECAUTION

Meloxicam is contraindicated to patients hypersensitive to this drug. Meloxicam should not be given to patients who have developed signs of asthma, nasal polyps, angioneurotic oedema or urticaria following the administration of aspirin or NSAIDs. Meloxicam is contraindicated to patients with active peptic ulcer during the last six months or a history of recurrent peptic ulcer disease, severe hepatic failure, non-dialysed severe renal failure, gastrointestinal bleeding, cerebrovascular bleeding or other bleeding disorders.

SIDE EFFECT

Nausea, vomiting, abdominal pain, dyspepsia, constipation or diarrhoea may occur. Ulcers or gastrointestinal bleeding may rarely occur. Skin rash, or urticaria may occur in some individuals. Oedema of the lower limbs may occur during treatment. Onset of an asthma attack has been reported in certain individuals allergic to aspirin or to other NSAIDs. Headache, vertigo or drowsiness may occur.

DRUG INTERACTION

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.

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USE IN PREGNANCY AND LACTATION

Pregnancy: It is advisable to avoid the administration of Meloxicam during pregnancy.

Lactation: It is unknown whether Meloxicam passes into mother's milk. Meloxicam should not be given to nursing mothers.

STORAGE CONDITION

Store Melcam[®] tablet in a cool & dry place and away from light. Store Melcam[®] suppository below 25°C protected from light and moisture.

HOW SUPPLIED

Melcam[®] 7.5 tablet : Box containing 10 x 10 tablets in blister pack.

Melcam[®] 15 tablet : Box containing 5 x 10 tablets in blister pack.

Melcam[®] 7.5 suppository : Box containing 2 x 5 suppository in blister pack.

Melcam[®] 15 suppository : Box containing 2 x 5 suppository in blister pack.

