# Selektine®
Meloxicam

**Composition:**
Meloxicam.
*Excipients:* Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, colloidal anhydrous silica and sodium laurisulfate.

**Properties:**
Meloxicam, the active ingredient of **Selektine®**, is a non-steroidal anti-inflammatory drug (NSAID) of the enolic acid class. Meloxicam has shown more potent inhibition of the biosynthesis of prostaglandins at the site of inflammation than in the gastric mucosa or the kidney. This was explained by meloxicam's selective inhibition of COX-2 isoform (inducible isoform) of the cyclo-oxygenase enzyme relative to COX-1. The absolute availability of meloxicam is around 89% after oral administration, and almost metabolized completely in the liver to pharmacologically inactive metabolites. It is around 99.4% bound to human plasma proteins.

**Indications:**
**Selektine®** is indicated for symptomatic treatment of:
- Rheumatoid arthritis.
- Osteoarthritis (arthrosis, degenerative joint disease).
- Ankylosing spondylitis.

**Dosage and administration:**
- Rheumatoid arthritis and ankylosing spondylitis: 15 mg once daily. Dose may be reduced to 7.5 mg once daily according to the therapeutic response.
- Osteoarthritis: 7.5 mg once daily. When needed, dose may be increased to 15 mg once daily.
- In patients with increased risks of adverse reactions: Start treatment at the dose of 7.5 mg daily.
- The maximum recommended daily dose of **Selektine®** is 15 mg.
- Dosage for children has not been established.
- **Selektine®** tablets should be swallowed with water or any suitable liquid, and to be taken with food.

**Contraindications:**
- Known hypersensitivity to meloxicam or any component of this product. There is potential for cross sensitivity to acetyl salicylic acid and other nonsteroidal anti-inflammatory drugs.
- As with other NSAIDs, meloxicam should not be given to patients who have developed signs of asthma or nasal polyps or angio-edema following the administration of acetylsalicylic acid or any other NSAIDs.
- Active peptic ulceration.
- Patients below 15 years of age.
- Severe hepatic or renal insufficiency.

**Drug interactions:**
- No interactions were detected with respect to the concomitant administration of meloxicam with antacids, cimetidine, digoxin or furosemide.
- As with other NSAIDs, concomitant administration with other drugs may lead to interactions, as:
- Reducing the effect of antihypertensive drugs (e.g., beta-blockers, ACE- inhibitors, vasodilators, and diuretics) may occur due to their concomitant administration with NSAIDs.
- It is not advised to take more than one NSAID at a same time, due to the expected synergistic action, which may lead to an increased risk of gastrointestinal ulceration and bleeding.
- Using NSAIDs with oral anticoagulants, ticlopidine, systemically administered heparin or thrombolytics may lead to an increased risk of bleeding. If this is the case, close monitoring of the effects of the anticoagulants is required.
- If taken with lithium, NSAIDs have been reported to increase lithium plasma levels.
- NSAIDs may increase the heamatological toxicity of methotrexate.
- NSAIDs decrease the efficacy of intrautrine devices.
- Cholestyramine binds meloxicam in the gastrointestinal tract leading to a faster elimination of meloxicam.
- Nephrotoxicity of cyclosporin may be enhanced by NSAIDs.

**Warnings:**
- Meloxicam should be withdrawn if peptic ulceration or gastrointestinal bleeding occurs.
- Special attention should be paid in patients reporting mucocutaneous adverse events and consideration given to discontinuing meloxicam.

**Precautions:**
- As with other NSAIDs, meloxicam should be given with caution to patients with a history of upper gastrointestinal disease and in patients receiving treatment with anticoagulants.
- If NSAIDs are to be given to dehydrated patients receiving diuretics, patients should be adequately hydrated and monitored for renal function prior to initiating treatment due to potential acute renal insufficiency caused by the use of NSAIDs in those patients. Do not exceed 7.5 mg/day of meloxicam in patients with end-stage renal failure on hemodialysis. No need to make dose reduction in patients with mild to moderate renal impairment in which creatinine clearance is greater than 25 ml/min.
- As with most other NSAIDs, meloxicam should be stopped and follow up tests carried out if a large or persistent increase in serum levels of transaminases or other liver function parameters have been reported.
- As with other NSAIDs, caution should be exercised in treating the elderly patients who are more likely to be suffering from impaired renal, hepatic or cardiac function.
- **Pregnancy:**
- 1st and 2nd trimester of pregnancy: **Category C**, there are no adequate and well controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- 3rd trimester of pregnancy: **Category D.**
- **Lactation:** Studies of meloxicam excretion in human milk have not been conducted. Meloxicam should not be used during breastfeeding.

**Adverse reactions:**
- Due to its preferential COX-2 inhibition, meloxicam has shown less gastrointestinal side effects - such as, oesophagitis, gastrointestinal bleeding, gastrointestinal perforation, colitis and gastroduodenal ulcer- than other NSAIDs.
- The following side effects may occur: Dyspepsia, nausea, vomiting, abdominal pain, flatulence, constipation, diarrhea, transitory abnormalities of liver function parameters, anemia, disturbances of blood count, stomatitis, urticaria, pruritus, skin rash, photosensitisation, onset of acute asthma, lightheadedness, headache, vertigo, tinnitus, drowsiness, oedema, increase of blood pressure, palpitations, flushes and abnormal renal function parameters (increased serum creatinine and/or serum urea).

**Overdosage:**
There is no known antidote for meloxicam. In case of overdosage, gastric lavage and administration of cholestyramine to accelerate the elimination of meloxicam can be done.

**Information for the patient:**
- **Selektine®** tablets should be swallowed with water or any suitable liquid, and to be taken with food.
- Inform your doctor if you have or had any GI problems, any allergic problems or asthma.
- Do not use alcohol, medications containing aspirin or salicylates, or other NSAIDs without consulting prescriber.

**Presentations:**
**Selektine®** 7.5 mg Tablets: Each tablet contains 7.5 mg Meloxicam in packs of 10 tablets and 30 tablets.
**Selekti** 15 mg Tablets: Each tablet contains 15 mg Meloxicam in packs of 10 tablets and 30 tablets

* Some presentations may not be available in certain countries.

(This is a medicament - keep medicaments out of the reach of children)

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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