Neoxicam

Meloxicam

Tablets
Anti-inflammatory / Analgesic / Antipyretic

Composition

Active ingredient:
Each tablet contains 7.5mg or 15mg of Meloxicam BP.

Inactive ingredients:
Lactose, Hypromellose, Microcrystalline Cellulose, Sodium Starch Glycolate, Colloidal Anhydrous Silica and Magnesium Stearate.

Properties :
Neoxicam is a non-steroidal anti-inflammatory drug with selective inhibition of COX-2 iso-enzyme. It enjoys a favourable safety profile due to this preferential inhibition of COX-2 iso-enzyme. Thus Neoxicam has been observed to provide benefits in suppression of pain & inflammation without GI complications in short-term therapy. After oral administration, Neoxicam is well absorbed. It achieves a peak plasma concentration within 5 hours after a single dose of 7.5mg. Neoxicam has plasma elimination half life of approximately 20 hours. Its excretion is mainly in the form of metabolites and it occurs to equal extents in urine and faeces.

Indications :
Neoxicam is indicated for symptomatic treatment in painful conditions of acute osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

Dosage :
The lowest dose of Neoxicam should be sought for each patient. For treatment of rheumatoid arthritis and ankylosing spondylitis, a starting dose of 15mg once daily is recommended. Dose may be reduced to 7.5mg once daily depending on therapeutic response. For treatment of osteoarthritis, a starting dose of 7.5mg once daily is recommended which may be increased to 15mg once daily. Maximum recommended daily dose is 15mg. The daily dose should be taken with a liquid during a meal.

Contraindications :
Neoxicam is contraindicated in patients with known hypersensitivity to meloxicam or one of other components. It should not be used in patients with asthma, nasal polyps, angioedema or urticaria following the administration of acetyl salicylic acid or other NSAIDs. Neoxicam should not be used in patients with active peptic ulcer, severe hepatic insufficiency and non-dialysed renal insufficiency. Neoxicam should not be used in children and adolescents aged less than 15 years. Neoxicam is contraindicated in gastrointestinal bleeding, cerebrovascular bleeding or other bleeding disorders.

Precautions :
Since Neoxicam metabolites are excreted in urine, patients with renal impairment must be closely monitored. Neoxicam should be used with caution in patients with hypertension or CHF due to risk of fluid retention and oedema.

Overdosage :
There is little experience with meloxicam overdosage. In some cases, 6 to 11 times the maximum recommended dose have been ingested followed by complete recovery. Cholestyramine is known to accelerate clearance of meloxicam.

Side Effects :
Digestive system: Dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhoea, stomatitis, oesophagitis. Rarely, peptic ulcers, gastrointestinal bleeding may occur, especially in the elderly.
Haematological system: Disturbances in the blood count such as anaemia, leucocytopenia, thrombocytopenia have been reported. Agranulocytosis has been reported rarely in patients who are also on a concomitant therapy with other potentially myelotoxic drugs.
Cutaneous reactions include pruritus, skin rash, urticaria and photosensitivity reactions. Rare effects include erythema multiforme, Stevens - Johnson syndrome and toxic epidermal necrolysis.
Hypersensitivity reactions have been reported. Anaphylactic reactions and angioedema have been reported rarely.
Onset of asthma attacks have been reported in those individuals who are allergic to aspirin or other NSAIDs.
CNS side effects include lightheadedness, headache, vertigo, tinnitus, drowsiness. Confusion, mood disorders, insomnia and nightmares have been reported rarely. Blurred vision has been reported rarely.
Oedema, oedema of the lower limbs, increase in blood pressure, palpitations and flushes may occur.
When patients are on meloxicam therapy, there is a possibility of disturbances of laboratory tests related to renal function such as raised creatinine or urea and transitory disturbances of liver function tests such as raised transaminases or bilirubin.
Rare cases of hepatitis have been reported.

Use in Pregnancy and Lactation :
Neoxicam is contraindicated in pregnancy and lactation.

Drug Interactions :
Concomitant therapy with oral anticoagulants, parenteral heparin and ticlopidine may cause increased risk of bleeding via inhibition of platelet function and cause damage to the gastroduodenal mucosa.
Co-administration with other NSAIDs, including high doses of salicylates may increase the risk of gastrointestinal ulcers and bleeding.
In patients who are on lithium therapy, administration of NSAIDs increases the blood lithium levels, which may reach toxic values. It is essential to carefully monitor lithium levels during therapy with meloxicam.
Anti-inflammatory drugs, when administered in patients on methotrexate, can lead to increased haematological toxicity of methotrexate. A case of agranulocytosis with meloxicam has been reported in a patient also treated with methotrexate. Therefore strict monitoring of blood cell count is recommended in such situations.
NSAIDs may enhance the nephrotoxicity of cyclosporin and hence during combined treatment renal function is to be measured.
In patients on diuretic therapy, treatment with NSAIDs is associated with a risk of acute renal failure in dehydrated patients. Therefore it is essential that the patient is adequately hydrated and renal function is monitored at the start of the treatment.
Combined therapy with pentoxifylline may increase the risk of bleeding, therefore close monitoring and checking bleeding time more often is recommended.
In patients on Zidovudine treatment, one week after the NSAID is started, there can be a risk of increased red cell line toxicity with severe anaemia. Hence it is essential to check CBC and reticulocyte count one to two weeks after starting treatment with the NSAIDs. Administration of NSAID along with antihypertensive agents such as beta-blockers, angiotensin converting enzyme inhibitors, diuretics may decrease the antihypertensive effect.
In patients who are on IUD there is a possible risk of impaired efficacy. When combined along with thrombolytics, there is an increased risk of bleeding.

Presentation :
Packs of 10, 30 and 100 tablets.

Storage :
Store in a dry place below 25°C.

INSTRUCTIONS TO THE PATIENT

This is a Medicament

- Medicament is a product, which 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 sold the medicament.
- The doctor and pharmacists are expert 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.

KEEP MEDICAMENT OUT OF THE REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists

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