MOVEN®

Meloxicam

ACTION

Meloxicam is an enolic class NSAID which has greater inhibitory action against the inducible isoform of cyclo-oxygenase COX-2, which is implicated in inflammatory response, than against the constitutive form of this enzyme COX-I ,inhibition of which is associated with gastric and renal side effects.

INDICATIONS

Moven is indicated for:

- symptomatic treatment of painful osteoarthritis.
- symptomatic treatment of rheumatoid arthritis.
- symptomatic treatment of ankylosing spondylitis.

DOSAGE AND ADMINISTRATION

- rheumatoid arthritis: Moven is given 15 mg orally once daily; which can be reduced to 7.5 mg/day if not tolerated.
- osteoarthritis: Moven may be given 7.5-15 mg once daily.
- ankylosing spondylitis: 15 mg/day.
- patients with increased risk factors should start treatment with 7.5 mg/day.
- dialysed severe renal failure: the dose should not exceed 7.5 mg/day.
- the maximum recommended dose is 15 mg/day.
- dosage for children and adolescents younger than 15 years old has not been established.
- capsules should be swallowed with water or other fluid in conjunction with food.

CONTRAINDICATIONS

Meloxicam is contraindicated in the following cases:

- known hypersensitivity to meloxicam, aspirin or NSAIDs.
- active GI bleeding.
- pregnant and breast feeding.
- severe hepatic insuffiency.
- non-dialysed severe renal insufficiency.
- patients younger than 15 years.
- Meloxicam should not be given to patients who have developed signs of asthma, nasal polyps, angio-oedema or urticaria following the administration of acetylsalicylic acid or other NSAIDs.

WARNINGS AND PRECAUTIONS

Use with caution in patients with history of GI bleeding. Patients with GI symptoms should be monitored, if appeared at any time during treatment, meloxicam should be withdrawn. The consequences of such events are more serious in elderly. Use with caution in patients receiving anticoagulants. NSAIDs inhibit the synthesis of renal PG that plays a supportive role in the maintenance of renal perfusion. In patients whose blood flow and blood volume are decreased, administration of an NSAID may precipitate in renal decompensation which recovers upon discontinuation of NSAID therapy. Patients at greater risk of such a reaction are dehydrated patients, those with congestive heart failure, liver cirrhosis, nephritic syndrome and overt renal disease, those receiving a diuretic or those having undergone major surgical procedures which led to hypovolemia. In such patients the volume of diuresis and the renal function should be carefully monitored at the beginning of therapy.

In rare instances NSAIDs may be the cause of interstitial nephritis, glumerulo-nephritis, renal medullary necrosis or nephritic syndrome. The dose of meloxicam in patients with end-stage renal failure on hemodialysis should not be higher than 7.5 mg, whereas, no dose reduction is necessary in patients with mild or moderate renal impairment (in patients with a creatinine clearance of greater than 25 ml/min).

Frail or debilitated patients may tolerate side effects less well and such patients should be carefully supervised. As with most other NSAIDs, occasional transient elevation of serum transaminases or other parameters of liver function have been reported. If the abnormalities are significant, meloxicam should be stopped. No dose reduction is required in patients with clinically stable liver cirrhosis.

Elderly patients should be carefully supervised when using meloxicam as other NSAIDs, for they are more likely to have impaired renal, hepatic or cardiac function.

Induction of Na, K and water retention and interference with the natriuretic effects of diuretics may occur with NSAIDs. Cardiac failure or hypertension maybe precipitated or exacerbated in susceptible patients as a result.

Patients who experience visual disturbances, drowsiness or other CNS disturbances should avoid driving and using machinery.

Drug Interactions

- Other NSAIDs including salicylates: Concomitant administration of more than one NSAID may increase the risk of gastrointestinal ulceration and bleeding through synergistic action.
- Oral anticoagulants, ticlopidine, systemically administered heparin, thrombolytics: increased risk of bleeding. If such co-prescribing cannot be avoided, close monitoring of the effects of anticoagulants is required
- lithium: NSAIDs have been reported to increase lithium plasma levels. It is recommended that plasma lithium levels be monitored when initiating, adjusting and discontinuing meloxicam.
- Methotrexate: As other NSAIDs meloxicam may increase the haematologic toxicity of methotrexate. In this situation, strict monitoring of blood cell count is recommended.
- Contraception: NSAIDs have been reported to decrease the efficacy of intrauterine devices
- Diuretics: Treatment with NSAIDs is associated with the potential for acute renal insufficiency in patients who are dehydrated. Patients receiving meloxicam and diuretics should be adequately hydrated and be monitored for renal function prior to initiating treatment.
- Antihypertensives (e.g. beta-blockers, ACE-inhibitors, vasodilators, diuretics): A reduced effect of the antihypertensive drug by inhibition of vasodilating prostaglandins has been reported during treatment with NSAIDs.
- Cholestyramine binds meloxicam in the gastrointestinal tract leading to a faster elimination of meloxicam.
- Nephrotoxicity of cyclosporin may be enhanced by NSAIDs via renal prostaglandin mediated effects. During combined treatment renal function is to be measured. Meloxicam is eliminated almost entirely by hepatic metabolism, of which approximately two thirds are mediated by cytochrome (CYP) P450 enzymes (CYP2C9 major pathway and CYP3A4 minor pathway) and one-third by other pathways, such as peroxidase oxidation. The potential for a pharmacokinetic interaction should be taken into account when meloxicam and drugs known to inhibit, or to be metabolized by, CYP2C9 and/or Cyp3A4 are administered concurrently. No relevant pharmacokinetic drug-drug interactions were detected with respect to the Concomitant administration of antacids, cimetidine, digoxin and furosemide. Interactions with oral antidiabetics cannot be excluded.

SIDE EFFECTS

The most commonly reported adverse effects are:

GIT: Dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhea (more frequent than 1%). Transitory abnormalities of liver function parameters e.g. raised transaminases or bilirubin eructation, esophagitis, gastroduodenal ulcer, occult or macroscopic gastrointestinal bleeding (between 0.1 and 1%). Gastrointestinal perforation, colitis, hepatitis, gastritis (less frequent than 0.1%).

Hematological: anemia (more frequent than 1%); Disturbances of blood count, including differential white cell count, leucopenia and thrombocytopenia.

Co-administration with methotrexate appears to be a predisposing factor to the onset of a cytopenia. *Dermatological:* Pruritis, skin rash (more frequent than 1%), stomatitis, urticaria (between 0.1 and 1%). Photosensitization, bullous reactions, erythema multiforme, stevens johnson Syndrome, toxic epidermal necrolysis may develop. (less frequent than 0.1%).

Respiratory: Onset of acute asthma has been reported (less frequent than 0.1%) in certain individuals following the administration of aspirin or other NSAIDs, including meloxicam.

CNS: Lightheadedness, headache (more frequent than 1 %); vertigo, tinnitus, drowsiness (between 0.1 and 1%), confusion, disorientation, alteration of mood (less than 0.1%).

Cardiovascular: Oedema (more frequent than 1 %); increase blood pressure, palpitation, flushes (between 0.1 and 1 %). *Genitourinary:* Abnormal renal function parameters increased serum creatinine and/ or serum urea (between 0.1 and 1 %), acute renal failure (less frequent than 0.1%).

Vision disorders: Conjunctivitis, visual disturbances including blurred vision (less frequent than 0.1%).

Hypersensitivity reactions: Angio-edema and immediate hypersensitivity reaction, including anaphylactoid/sinaphylactic reactions (less frequent than 0.1%).

OVERDOSAGE

In case of overdose, the standard measures of gastric evacuation and general supportive measures should be used as there is no known antidote. Trials has shown that cholestyramine accelerates the elimination of meloxicam.

STORAGE CONDITIONS

Store in a dry place below 30˚C.

PRESENTATIONS

Capsules:

MOVEN 7.5 mg	Meloxicam 7.5 mg/capsule
MOVEN 15 mg	Meloxicam 15 mg/capsule

Excipients: Lactose, Trisodium citrate, Maize starch, Colloidal silica, Magnesium stearate.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold 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.

The Arab Pharmaceutical Manufacturing Co.,
Suit - Jordan

Keep medicament out of the reach of children

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