Motion®
(Meloxicam)

Properties:
Motion® (meloxicam) is a potent nonsteroidal anti-inflammatory drug of the enolic acid class that shows anti-inflammatory, analgesic and antipyretic properties in all standard models of inflammation for the management of musculoskeletal and joints disorders with less gastrointestinal irritation and no ulcerogenic action. It is reported to be an inhibitor of the biosynthesis of prostaglandins, known mediators of inflammation. Meloxicam is known to be a selective inhibitor of the cyclooxygenase enzyme (COX-2) than against the enzyme (COX-1), inhibition of which is associated with gastric and renal side effects.

Indications:
Motion® is indicated for:
- Symptomatic treatment of painful osteoarthritis (arthrosis, degenerative joint disease).
- Symptomatic treatment of rheumatoid arthritis.
- Symptomatic treatment of ankylosing spondylitis.

Side Effects:
- **Common GI side effects**: nausea, vomiting, diarrhea, constipation, abdominal pain, dyspepsia, flatulence.
- **Dermatological effects**: pruritus, skin rash, stomatitis, urticaria, photosensitisation.
- **Hematological**: anemia, disturbances of blood count, including differential white cell count, leukopenia and thrombocytopenia.
- **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**: headache, vertigo, tinnitus, drowsiness.
- **Cardiovascular**: oedema, increase of blood pressure, palpitations, flushes.
- **Genitourinary**: abnormal renal function parameters, increased serum creatinine and/or serum urea.

Contraindications:
Meloxicam is contraindicated in the following cases:
- Known hypersensitivity to meloxicam, aspirin, or NSAIDs.
- Meloxicam should not be given to patients who have developed signs of asthma, nasal polyps, angioedema, or urticaria following the administration of acetylsalicylic acid or other NSAIDs.
- Active peptic ulceration.
- Severe hepatic insufficiency.
- Non-dialysed severe renal insufficiency.
- Children and adolescents aged less than 15 years.

Precautions:
- As with other NSAIDs caution should be exercised when treating patients with a history of upper gastrointestinal disease and in patients receiving treatment with anti-coagulants. Meloxicam should be withdrawn if peptic ulceration or gastrointestinal bleeding occurs.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.
- NSAIDs inhibit the synthesis of renal prostaglandins which play a supportive role in the maintenance of renal perfusion. In patients whose renal blood flow and blood volume are decreased, administration of an NSAID may precipitate overt renal decompensation which is typically followed by recovery to pretreatment state upon discontinuation of nonsteroidal anti-inflammatory therapy. Patients at greatest risk of such a reaction are dehydrated patients, those with congestive heart failure, liver cirrhosis, nephrotic syndrome and overt renal disease, those receiving a diuretic or those having undergone major surgical procedures which led to hypovolaemia. 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, glomerulonephritis, renal medullary necrosis or nephrotic syndrome. The dose of meloxicam in patients with end stage renal failure on hemodialysis should not be higher than 7.5mg. No dose reduction is required in patients with mild to moderate renal impairment (i.e. creatinine clearance > 25ml/min.).
- As with most other NSAIDs, occasional elevations of serum transaminases or other parameters of liver function have been reported. In most cases there have been small and transient increases above the normal range. If the abnormality is significant or persistent, meloxicam should be stopped and follow up tests carried out. No dose reduction is required in patients with clinically stable liver cirrhosis.
- Frail or debilitated patients may tolerate side effects less well and such patients should be carefully supervised. As with other NSAIDs caution should be used in the treatment of elderly patients who are more likely to be suffering from impaired renal, hepatic or cardiac function.
- There are no specific studies about effects on the ability to drive vehicles and to use machinery. However, when adverse effects such as vertigo and drowsiness occur it is advisable to refrain from these activities.

Pregnancy and Lactation:
Pregnancy category C/D (3rd trimester).
Although no teratogenic effects were seen in pre-clinical testing, meloxicam should not be used during pregnancy and breastfeeding.

Drug-Drug Interactions:
- **Concomitant administration of more than one NSAID** may increase the risk of gastrointestinal ulceration and bleeding through synergistic action.
- **Lithium**: NSAIDs have been reported to increase lithium plasma levels.
- **Methotrexate**: NSAIDs may increase the hematological toxicity of methotrexate.
- **Contraception**: NSAIDs decrease the efficacy of intrauterine devices.
- **Diuretics**: patients receiving meloxicam and diuretics are associated with the potential for acute renal insufficiency in patients who are dehydrated. Those patients should be adequately hydrated and be monitored for renal function prior to initiating treatment.
- **Antihypertensives** (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**: cholestyramine binds meloxicam in the gastrointestinal tract leading to a faster elimination of meloxicam.
- **Cyclosporin**: nephrotoxicity of cyclosporin may be enhanced by NSAIDs via renal prostaglandin mediated effects, so renal function is to be measured in these cases.
- **Oral anticoagulants, ticlopidine, systemically administered heparin, thrombolytics:** increased risk of bleeding. If such combinations can't be avoided, close monitoring of the effects of anticoagulants is required.

Overdosage:
In case of overdosage, the standard measures of gastric evacuation and general supportive measures should be used as there is no known antidote. It has been shown in a clinical trial that cholestyramine accelerates the elimination of meloxicam.

Dosage and Administration:
- **Motion®** for the treatment of osteoarthritis: the recommended starting dose is 7.5mg once/day. Some patients may receive additional benefit by increasing the dose to 15mg once/day.
- **Motion®** for the treatment of rheumatoid arthritis and ankylosing spondylitis: 15mg per day, according to the therapeutic response, the dose may be reduced to 7.5mg per day.
- The maximum recommended daily dose is 15mg.
- In patients with increased risks of adverse reactions, start treatment at the dose of 7.5mg/day.
- In dialysis patients with severe renal failure, the dose should not exceed 7.5mg/day.
- As a dosage for use in children has yet to be established, usage should be restricted to adults.
- Tablets should be swallowed with water or other fluid in conjunction with food.

Presentations:
Motion® 7.5 tablets, each tablet contains meloxicam B.P. in a pack of 10 and 30 tablets.
Motion® 15 tablets, each tablet contains meloxicam B.P. in a pack of 10 and 30 tablets.

Hospital packs are available.

Storage Conditions:
Store below 30°C.

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, method of use and the instructions of 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 prescription without consulting your doctor.
- Keep out of reach of children.

Manufactured by: Middle East Pharmaceutical Company - **MIDPHARMA** - Jordan
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