Moxalid®

Meloxicam

Injectable Solution (I.M) 15mg/1,5ml ampoule

NAME OF THE PRODUCT: MOXALID
COMPOSITION: Active ingredient: Meloxicam. Excipients: Meglumine, Glycofurol, Poloxamer 188, Sodium Chloride, Glycine, Sodium Hydroxide, Water for Injection.
DRUG FORMULATION: Solution for Injection.
CONCENTRATION OF ACTIVE INGREDIENT: Meloxicam 15 mg.
PRESENTATION: 5 glass vials containing 1.5 ml of the solution for injection are placed in a carton box along with the patient information leaflet.
THERAPEUTIC CATEGORY: It is a Non-Steroidal Anti-Inflammatory Drug (NSAID).
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WHAT YOU SHOULD KNOW ABOUT THE MEDICINE YOUR DOCTOR HAS PRESCRIBED
GENERAL INFORMATION: MELOXICAM, belongs to the non-steroidal anti-inflammatory drugs that also have an antipyretic effect. It acts by inhibiting the formation of prostaglandins, which are considered to cause the symptoms of inflammation in the area of the damage.
INDICATIONS: MOXALID is indicated for:
- Short-term symptomatic treatment of acute exacerbations of osteoarthritis.
- Long-term symptomatic treatment of rheumatoid arthritis or ankylosing spondylitis.

CONTRA - INDICATIONS: Drugs can help in sickness, but they can also cause problems if not taken according to your doctor's prescriptions.
Before taking the particular drug you should inform your doctor in the following cases: If:
- You ever had an allergic or unusual reaction to meloxicam or any of the excipients contained in the formulation, or hypersensitivity in substances with similar action, e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and salicylic acid.
- You have asthma, nasal polyps, angioneurotic oedema, or itching after administration of salicylic acid or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
- You had active peptic ulcer in the past 6 months or a history of recurring peptic ulcer.
- You have serious renal failure.
- You have serious renal failure that does not allow for haemodialysis.
- You are pregnant or lactating.
- You had gastrointestinal haemorrhage, had stroke or other haemorrhagic disturbances.
- You have disturbances of homeostasis or receiving simultaneous treatment with anticoagulants (contraindication associated with the route of administration).
- You have serious, non-controllable heart insufficiency.

Moreover, the drug should not be administered in children under 15 years old.
SPECIAL PRECAUTIONS AND WARNING DURING USE:
General:
- Possible history of oesophagitis, gastritis, and/or peptic ulcer must be investigated to ensure full recovery before initiation of treatment with meloxicam. Attention should be given to the possibility of recurrence, in patients that have been treated with meloxicam and in patients with a history of this kind of problems.
- Patients with gastrointestinal symptoms or history of gastrointestinal disease (i.e. ulcerative colitis, Crohn's disease) must be monitored for peptic disturbances, particularly for gastrointestinal haemorrhage.
- As in all NSAIDs, gastric haemorrhage or ulceration/puncture, in rare cases fatal, have been reported with meloxicam at any point during the course of treatment with or without warning signs or without previous history of serious gastrointestinal events. Gastrointestinal bleeding or ulceration/puncture have generally more serious consequences in the elderly (see "Special cases in the population")
- If gastrointestinal bleeding or ulceration does occur in patients receiving meloxicam, administration should be discontinued.
- A possible appearance of serious skin reaction and serious, life-threatening hypersensitivity reactions (i.e. anaphylactic shock) is known to occur with the administration of NSAIDs, including oxicams. In these cases, administration of meloxicam should be discontinued immediately and careful monitoring of the condition should occur.
- In rare cases , NSAIDs may be the cause of intermediate nephritis, glomerulonephritis, necrotic thelitis or nephritic syndrome.
- As with most NSAIDs, there have been reported occasional increases in the transaminase, serum bilirubin levels, or other parameters of renal function, or increases in the serum creatinine and blood urea, or other disturbances. Most cases are slight and reversible disturbances. In case such a disturbance is serious or persistent, administration of meloxicam should be discontinued and the case to be appropriately investigated.
- Administration of NSAIDs may cause increase in sodium and potassium levels, water retention and inhibition of the sodium-removing action of diuretics, resulting in possible deterioration of the condition of patients with heart failure or hypertension.
- NSAIDs inhibit the synthesis of renal prostaglandins, which are implicated in the maintenance of renal haematosis in patients with reduced renal blood flow and blood volume. Administration of NSAIDs in such cases may result to the lack of counteraction of latent renal failure. However, renal function returns to its initial level once treatment is discontinued. These dangers appertains all elderly patients, patients with heart failure, kidney cirrhosis, nephritic syndrome or renal failure, as well as patients receiving diuretics or have been subjected in serious operation that has led to reduction of blood volume. In these patients careful monitoring of the diuresis and renal function should be performed during treatment.
- Adverse reactions are often less tolerated in elderly, sensitive or weakened persons, which therefore need closer monitoring. As in the case of other NSAIDs, special attention is needed in the treatment of the elderly, who often present abnormal renal, hepatic and/or heart function.
- The recommended maximum daily dose should neither be exceeded in case of insufficient therapeutic result, nor should another NSAID be added to the treatment, because the toxicity may be increased, while no therapeutic advantage has been observed.
- Meloxicam, as the other NSAIDs, may hide symptoms of underlying infectious disease.
- Use of meloxicam, as of any other drug known to inhibit the synthesis of cyclooxygenase/prostaglandin, may affect the reproductive ability and is not recommended in women trying to conceive. Women having difficulty in conceiving, or under investigation for under-fertility, interruption of meloxicam administration should be examined.

Pregnancy:
- In animal studies, fetal lethality has been reported in doses higher than those used clinically.
- It is suggested to avoid administration of meloxicam during pregnancy.
- During the last three months of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to cardiopulmonary (pulmonary hypertension with premature contraction of the arterial pore) and renal toxicity or to inhibit contraction of the uterus. This action on the uterus has been associated with difficult and prolonged delivery in animals.

Therefore, all NSAIDs are definitely contraindicated in the last 3 months of pregnancy.
Lactation: NSAIDs pass on to lactating milk. Meloxicam should therefore not be used in lactating women.
Effect in the ability to drive and use machines: Concurrent administration of NSAIDs may increase the danger of gastrointestinal ulcer and gastrointestinal haemorrhage through cooperative effect.

Not recommended combinations:

· With other NSAIDs including salicylates (acetylsalicylic acid ≤3g/day)

· With lithium. If the combination is necessary, lithium plasma concentrations must be observed carefully during the initiation, adjusting and termination of treatment with meloxicam.

· With oral anticoagulants. If it is impossible to avoid such a combination careful observation of the INR is required.

· Methotrexate in doses 15 mg/week or bigger.

Careful consideration is required in the simultaneous administration with diuretics, cyclosporine, methotrexate in low doses less than 15 mg/week, thrombolytic and anti-platelet drugs, angiotensin converting enzyme (ACE) inhibitors, angiotensin II agonists, and other antihypertension factors.

It should also be taken into account that NSAIDs may reduce the effectiveness of endometrial devices.

Simultaneous administration of antioxidants, cimetidine, digoxine has not resulted to significant pharmacokinetic interactions with meloxicam. Cholestyramine accelerates the excretion of meloxicam via retention in the digestive tract.

Before taking this product you should also inform your doctor about any other drug you may be taking, even without medical prescription.

DOSAGE AND ADMINISTRATION:

Exacerbations of osteoarthritis: 7.5mg/day (half an ampoule). If necessary, in case of lack of improvement, the dose can be increased in 15mg/day (one ampoule).

Reumatoid arthritis, ankylosing spondylitis: 15mg/day (one ampoule). Depending on the therapeutic response, the dose can be reduced to 7.5mg/day (half an ampoule).

The dose should not exceed 15mg/day.

Special Cases in Population: Elderly patients and patients with increased risk for adverse reactions: The recommended dose for long-term treatment of elderly patients is 7.5mg/day. In patients with increased risk of adverse effects, treatment should begin with 7.5mg/day.

Renal Failure: In patients haemodialysis in serious forms of renal failure, dose should not exceed 7.5 mg/day. No reduction of the dose is needed for patients with mild or moderate renal insufficiency (i.e. patients with creatinine clearance bigger than 25 ml/min). (For patients with serious renal failure that does not take haemodialysis see "Contraindications").

Hepatic Failure: No dose reduction is required in patients with mild to moderate hepatic insufficiency. (For patients with serious hepatic insufficiency see "Contraindications").

Children: MOXALID should not be used for children under 15 years of age.

OVERDOSAGE: Symptoms resulting from acute overdosage of NSAIDs are usually limited to lethargy, sleepiness, nausea, vomiting, epigastiral aches which are generally reversible with supportive therapy. Gastric bleeding may also occur. Heay poisoning may lead to hypertension, acute renal failure, hepatic malfunction, respiratory suppression, coma, spasms, cardiovascular collapse and cardiac arrest. Anaphylactic reactions have been reported after administration of NSAID and may appear after receiving excessive dose.

MANAGEMENT OF OVERDOSAGE: After overdosing with a NSAID patients should be treated with symptomatic and supportive measures. Accelerated removal of meloxicam via oral administration of 4 g cholestyramine given three times daily has been demonstrated during a clinical trial.

WHAT YOU SHOULD KNOW IN CASE YOU HAVE OMITTED A DOSE: If you omitted a dose you have to take it the sooner possible. Yet, if the time for the next dose is approaching, do not take the dose you omitted but continue the therapy as you should.

UNDESIRABLE EFFECTS: General Description: The following undesirable effects have been reported, which may be connected to the administration of meloxicam. The frequency of appearance presented below is based on respective frequencies in clinical trials, independently of any aetiological relationship. The information is based on clinical studies, on which 3750 patients took part to whom oral doses of meloxicam (7.5 or 15 mg, tabs or caps) were administered to them for a period up to 18 months (average treatment period 127 days). To these, there are also included undesirable effects which may have an aetiological connection to the administration of meloxicam, which have arisen from reports received in connection to the product after authorisation.

The undesirable effects have been categorized according to the frequency that they appear, as follows: Very common (>1/10), Common (<1/10, >1/100), Uncommon (<1/100, >1/1000), Rare (<1/1 000, >1/10000), Very rare (<1/1 0000).

Table of undesirable effects

Blood and Lymph system disturbances: Common: Anaemia. / Uncommon: Disturbances on the shape of blood cells: Leucopenia, thrombocytopenia, agranulocytosis.

Immune system disturbances: Rare: Anaphylactic/Aanaphylactoid reactions.

Psychiatric disturbances: Rare: Mood disturbances, sleeplessness and nightmares.

Nervous system disorders: Common: Dizziness, headaches. / Uncommon: Drowsiness, convulsions, drowsiness. / Rare: Anxiety.

Visual disorders: Rare: Visual disorders include dimming of vision.

Cardio-vascular disorders: Rare: Palpitations.

Arterial disorders: Uncommon: Elevated blood pressure, flushing.

Pulmonary disorders, of the thorax and meso-thorax: Rare: Introduction of asthma attack in certain persons allergic to aspirin and NSAID.

Gastrointestinal disorders: Common: Dyspepsia, nausea, vomiting, abdominal pains, constipation, diarrhoea. / Uncommon: Gastro-intestinal bleeding, peptic ulcers, oesophagostomiasis. / Rare: Gastro-intestinal ulceration, gastritis, colitis. / Peptic ulcers, ulceration or gastro-intestinal bleeding that may occur, may be serious especially in the elderly.

Kidney and liver disorders: Uncommon: Periodic disorders of the hepatic function (e.g. increase in transaminases or bile cholerithrine). / Rare: Hepatitis.

Skin and tissue disorders: Common: Pruritis, rashes. / Uncommon: Dyspnoea. / Rare: Stevens-Johnson syndrome and toxic epidermal necrosis, angioedema like polymorphous erythraemia, reactions to photosensitivity.

Renal and urea disorders: Uncommon: Disorders of the laboratory tests that investigate renal function (i.e. increase of creatinine or of urea). Rare: Kidney failure.

General disorders due to site of administration: Common: Oedema, including oedema of toes.

Information regarding serious individual and/or common undesirable effects: Individual cases of agranulocytosis had been reported in patients that took meloxicam and other musculo-toxic medications.

EXPIRY DATE OF THIS PRODUCT: Do not use the product after the date that is printed on the vial and the external packaging.

STORAGE INSTRUCTIONS FOR THIS PRODUCT: The vial should be stored below 25°C, protected from light.

DATE OF LAST UPDATE OF THIS LEAFLET: 6/12/2004

INFORMATION ON THE RATIONAL USE OF MEDICINES

- This medicine has been prescribed by your doctor only for your specific medical problem. You should not give it to other individuals or use it for any other condition, without previous consultation with your doctor.
- If during your therapy there is any problem with the medicine, you should notify your doctor or pharmacist.
- If you have any questions about the information concerning the drug you are taking or if you need more information about your medical problem, do not hesitate to ask your doctor or pharmacist.
- To be effective and safe the prescribed drug should be used according to the instructions given to you.
- For your health and safety you must read carefully all the information regarding the drug you have been prescribed.
- Do not store medicines in bathroom cupboards; heat and moisture may alter them and make them hazardous to your health.
- Do not keep medicines you do not need any more, or those that have expired.
- For greater safety keep all medicines out of the reach of children.

THIS MEDICINE IS TO BE TAKEN ONLY BY DOCTOR'S PRESCRIPTION