

ALEXICAM

(Meloxicam BP)
Tablets 7.5mg, 15mg

DESCRIPTION:

ALEXICAM (Meloxicam) is a nonsteroidal anti-inflammatory drug (NSAID), which selectively inhibits cyclooxygenase-2 (Cox-2). ALEXICAM (Meloxicam) has anti-inflammatory, analgesic and antipyretic activities.

INDICATIONS:

ALEXICAM (Meloxicam) is indicated for

1. The relief of signs and symptoms of acute and chronic osteoarthritis
 2. The relief of signs and symptoms of acute and chronic rheumatoid arthritis
- The relief of signs and symptoms of back pain (sciatica and lumbago)
 - The treatment of primary dysmenorrhea.
 - Relief of pain.

DOSAGE AND ADMINISTRATION:

The usual recommended dosage of ALEXICAM (Meloxicam) is 7.5 mg or 15 mg once a day. In acute painful conditions with severe pain like rheumatoid arthritis preferred dose is 15 mg Per day. The usual maximum daily dose is 15 mg.

CONTRAINDICATIONS:

ALEXICAM (Meloxicam) is contraindicated in patients having hypersensitivity to the molecule. It is also contraindicated in patients with known peptic ulcer.

PRECAUTIONS:

Hepatic Effects:

Few patients taking ALEXICAM (Meloxicam) report elevation of liver enzymes. Rarely the elevation can be more three-folds the normal values, jaundice, fulminant hepatitis, hepatic necrosis and hepatic failure are rarely encountered in patients taking ALEXICAM (Meloxicam).

Renal Effects:

With pre-existing compromised kidney functions, it is advised to be cautious while using NSAIDs including ALEXICAM (Meloxicam). Physiological renal blood flow is dependent upon normal synthesis of prostaglandins. Interference of prostaglandin synthesis can cause renal decompensation, heart failure, dehydration and use of diuretics make patient more prone to such effects.

Special Population:

Hepatic Insufficiency:

In case of mild to moderate hepatic insufficiency dose adjustment of ALEXICAM (Meloxicam) is not needed. There is not enough data on pharmacokinetics in severe hepatic insufficiency.

Renal Insufficiency:

In patients having creatinine clearance of more than 15 ml/min, there is no need to bring about the adjustment of dose of ALEXICAM (Meloxicam). In severe renal failure, however, enough studies have not been conducted to determine the dose.

Pregnancy:

Because of lack of data in pregnant women, ALEXICAM (Meloxicam) should only be used during pregnancy if benefits clearly outweigh the risks to fetus and mother. Like other NSAIDs, ALEXICAM (Meloxicam) can cause premature closure of ductus arteriosus, therefore it should not be used in the third trimester of pregnancy. It should also be kept in mind that inhibition of prostaglandin synthesis can also cause increase in delivery time.

Nursing Mother:

ALEXICAM (Meloxicam) has been shown to be excreted in milk of lactating rats. Therefore the use of ALEXICAM (Meloxicam) should be avoided in lactating women or a decision should be made to discontinue nursing.

Children:

The efficacy and safety of ALEXICAM (Meloxicam) has not been well studied in patient less than 18 years of age.

Elderly Patients:

In older patients of more than 65 years of age the administration of ALEXICAM (Meloxicam) should be carefully monitored.

Drug Interaction:

ALEXICAM (Meloxicam) can exhibit interaction with following drug

- **Aspirin:** concomitant administration of ALEXICAM (Meloxicam) can increase adverse effects.
- **Lithium:** If given with Lithium, ALEXICAM (Meloxicam) can reduce renal clearance and increase serum concentration of Lithium. Careful monitoring of Lithium treatment is advised when ALEXICAM (Meloxicam) is used concomitantly.
- **ACE Inhibitors:**
Anti hypertensive effect of ACE inhibitors is reduced by concomitant administration of ALEXICAM (Meloxicam).
- **Warfarin:**
Anticoagulant effect of ALEXICAM (Meloxicam) can potentiate the effect of warfarin.

Side Effect:

ALEXICAM (Meloxicam) is generally well tolerated as compared to non-selective NSAIDs. Owing to selective inhibition of cyclooxygenase-2 the incidence of gastrointestinal side effects is low with ALEXICAM (Meloxicam).

General:

Allergic reactions, anaphylactic reactions, fatigue, malaise, face edema, fever and hot flushes

Gastrointestinal:

Dry mouth, eructation, esophagitis, duodenal ulcer, gastric ulcer, gastritis, gastroesophageal reflux, gastrointestinal hemorrhage, hematemesis, hemorrhagic gastric ulcer, melena, pancreatitis, stomatitis and colitis.

Cardiovascular System:

Cardiac failure, vasculitis, hypertension, hypotension, arrhythmia, palpitation and tachycardia.

Hematologic:

Leukopenia, thrombocytopenia, agranulocytosis and purpura.

Liver:

Increase in ALT or AST, bilirubinemia increased GGT, hepatitis and liver failure.

Central and peripheral nervous system:

Tremor, vertigo, convulsions and paresthesia.

Psychiatric Disorders:

Anxiety, increased appetite, somnolence, confusion, depression and nervousness.

Respiratory system:

Asthma and bronchospasm.

Skin and Appendages:

Urticaria, pruritus, angioedema, bullous eruption, alopecia, photosensitivity reaction, Steven-Johnson syndrome, erythema multiforme, increased sweating, toxic epidermal necrolysis.

Urinary system:

Albuminuria, hematuria, increased BUN, increased serum creatinine, renal failure.

Presentation:

ALEXICAM 7.5 mg TABLETS: Each tab contains Meloxicam 7.5 mg in blister pack of 1x10s

ALEXICAM 15 mg TABLETS: Each tab contains Meloxicam 15 mg in blister pack of 1x10s



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