Meloxicam, an oxicam derivative, is a member of the non-opioid analgesics, anti-inflammatory, and anti-rheumatic drug family (NSAIDs). Its unique structure, with the presence of an enolic acid group and an aromatic ring, allows it to have unique properties compared to other NSAIDs.

**Mechanism of Action**

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) that inhibits the synthesis of prostaglandins, which are pain and inflammation mediators. It works by inhibiting the COX-1 and COX-2 enzymes, thereby reducing the production of prostaglandins and other inflammatory substances.

**Pharmacokinetics**

Following oral administration, meloxicam is well absorbed with peak plasma concentrations being achieved within 4 to 5 hours. It has a long terminal elimination half-life of approximately 18 hours, allowing for once-daily dosing. Meloxicam is extensively metabolized in the liver, with less than 10% of the dose excreted in the urine as unchanged drug. The major metabolites are 5'-hydroxymethyl meloxicam and 5'-carboxy meloxicam, which represent approximately 60% and 40% of the dose, respectively.

**Elimination**

Meloxicam is eliminated primarily by renal excretion. In patients with normal renal function, approximately 6% of the dose is excreted in the urine as unchanged meloxicam, with the remainder being eliminated as metabolites. In patients with renal impairment, the elimination half-life of meloxicam increases.

**Special Populations**

- **Gender:** Gender does not appear to affect the pharmacokinetics of meloxicam. Elderly females (≥65 years of age) had a 47% higher AUC compared to elderly males, but the clinical significance of this finding is unclear.
- **Renal Insufficiency:** There is limited data on the use of meloxicam in patients with severe renal insufficiency (creatinine clearance <30 mL/min). Dose adjustment is recommended in these patients.
- **Hepatic Insufficiency:** Meloxicam is metabolized by the liver, and patients with severe hepatic impairment (Child-Pugh Class III) should be monitored closely.

**Dose and Administration**

Table 1 provides single dose and steady-state pharmacokinetic parameters for oral meloxicam 7.5 mg and 15 mg doses.

**Contraindications**

- NSAIDs, including meloxicam, are contraindicated in patients who have had an anaphylactic or serious skin reaction to a previous NSAID.
- Patients with a history of aspirin allergy should usually not receive meloxicam.

**Warnings**

- **Gastrointestinal Bleeding and Ulceration:** NSAIDs, including meloxicam, increase the risk of serious gastrointestinal adverse events, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.
- **Cardiovascular Events:** NSAIDs increase the risk of serious cardiovascular thrombotic events, including MI and stroke, in patients with cardiovascular disease or risk factors for cardiovascular disease. The increased risk may be quantified by a relative risk increase (i.e., RR increase) or an absolute risk increase (i.e., ARI increase). Meloxicam's cardiovascular safety profile should be monitored in patients with cardiovascular disease or risk factors for cardiovascular disease.

**Clinical Trials**

- Clinical trials have shown meloxicam to be effective in the treatment of osteoarthritis of the knee and hip.
- Meloxicam has been studied in patients with osteoarthritis and rheumatoid arthritis, and has been shown to be effective in reducing pain and improving function.

**Warnings**

- Meloxicam is contraindicated in patients with a history of aspirin allergy.
- Patients with severe renal insufficiency should be monitored closely.
- Meloxicam should be used cautiously in patients with severe hepatic insufficiency.

**Pharmacology**

- Meloxicam is a member of the oxicam class, which includes other NSAIDs such as naproxen and ibuprofen.
- Meloxicam has a unique structure, with an enolic acid group and an aromatic ring, which allows for improved pharmacokinetic properties compared to other NSAIDs.

**Precautions**

- Meloxicam should be used with caution in patients with a history of ulcer disease or hemorrhage.
- Blood pressure should be monitored in patients receiving meloxicam.

**Adverse Effects**

- Adverse effects of meloxicam include gastrointestinal events, such as constipation, diarrhea, and peptic ulcer disease.
- Other adverse effects include edema, dizziness, headache, and increased liver enzymes.

**Drug Interactions**

- Meloxicam can interact with other drugs, such as those that can affect renal function or liver function.
- Patients taking meloxicam should be monitored for potential drug interactions.

**Dosage and Administration**

- Meloxicam is available as a tablet formulation, with recommended doses of 7.5 mg or 15 mg. The duration of use should be consistent with the treatment of osteoarthritis.
- Meloxicam tablets can be administered with or without food, but may be associated with an increased risk of gastrointestinal adverse events in the elderly.

**Contraindications**

- Meloxicam is contraindicated in patients with a history of aspirin allergy.
- Patients with severe renal insufficiency should be monitored closely.
- Meloxicam should be used cautiously in patients with severe hepatic insufficiency.

**Warnings**

- Meloxicam is contraindicated in patients with a history of aspirin allergy.
- Patients with severe renal insufficiency should be monitored closely.
- Meloxicam should be used cautiously in patients with severe hepatic insufficiency.
Their hemoglobin or hematocrit should be checked if they exhibit any signs or symptoms of anemia. Caution is also recommended in patients with pre-existing kidney disease (see Boxed Warning).

Hepatic Effects

Fulminant hepatitis, liver necrosis and hepatic failure, some of them with fatal outcomes have been reported in clinical trials with NSAIDs. In addition, rare cases of severe hepatic reactions, including jaundice and fatal hepatic failure, have been reported in patients treated with meloxicam tablets. These laboratory abnormalities may progress, may remain unchanged, or may resolve with or without discontinuation of meloxicam tablets. None of these events, however, have been reported with meloxicam tablets. Therefore, these reactions must be considered when evaluating the risk-benefit ratio of meloxicam tablets in any patient treated with NSAIDs. These events can occur at any time during therapy and, if they do occur, they can lead to fatal outcomes. Patients with pre-existing liver disease are at higher risk for these reactions.

Hepatic Effects are discussed in detail in PRECAUTIONS (12.13) and within WARNINGS (1.3).

Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs. These abnormalities may be asymptomatic and self-limiting. In those patients in whom liver reactions occur, the laboratory abnormalities may progress, remain unchanged, or resolve with or without discontinuation of meloxicam tablets. If the abnormal liver test results are progressive or associated with clinically significant symptoms, meloxicam tablets should be discontinued.

Hepatic Effects are further discussed in WARNINGS (5.7).

Skin Reactions

Fulminant hepatic failure and eosinophilia (together with eosinophilia and fever) and angioedema have been reported in late pregnancy in women treated with meloxicam tablets. These reactions are discussed in PRECAUTIONS (9.8) and WARNINGS (9.7).

Skin Reactions are further discussed in WARNINGS (9.6).

Pregnancy

There are no adequate and well-controlled studies in pregnant women. Use of NSAIDs, including meloxicam, during the second and third trimesters of pregnancy may cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the possibility of pregnancy is known prior to starting the drug, the patient should be apprised of the potential risk for fetal harm. However, even though data are lacking, it is generally agreed that in situations where there is an urgent need for the maternal therapy and no safer drug can be given, the benefit-risk ratio for meloxicam tablets should be considered. However, no adequate and well-controlled studies in late pregnancy in women treated with meloxicam tablets have been reported. They should be avoided in late pregnancy.

Skin Reactions are further discussed in WARNINGS (9.7).

Breastfeeding

It is not known whether meloxicam is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when meloxicam tablets are administered to a nursing mother.

Pre-existing Asthma

Serious, occasionally fatal, anaphylactoid reactions and urticaria have been reported in patients with a history of asthma. These reactions are discussed in CONTRAINDICATIONS (1.3) and WARNINGS (7.3).

Anaphylactoid Reactions are discussed in WARNINGS (7.3).

Fibromyalgia

Meloxicam tablets for treating fibromyalgia have been proven to be effective and well tolerated in properly controlled clinical trials. The results of these trials are discussed in CLINICAL PHARMACOLOGY (12.5).

Fibromyalgia is discussed in CLINICAL PHARMACOLOGY (12.5).
The effects of meloxicam tablets on labor and delivery in pregnant women are unknown.

Reproductive Toxicology
In animal reproduction studies, meloxicam did not cause any adverse effects on the fetal outcome in rats when dams were given meloxicam 2 weeks prior to mating and during early embryonic organogenesis. An increased incidence of stillbirths was observed when rats were given oral doses ≥1 mg/kg/day (0.5-fold the human dose, as noted above) for 99 weeks.

In a study conducted in healthy subjects, mean pre-dose lithium concentration and AUC were increased by 23% in lithium-treated subjects receiving meloxicam tablets. In other subjects, meloxicam did not alter warfarin pharmacokinetics. Meloxicam did not have a significant effect on the pharmacokinetics of methotrexate taken once weekly. Meloxicam did not have a significant effect on the pharmacokinetics of furosemide.

Furosemide
In a study conducted in healthy subjects, mean pre-dose lithium concentration and AUC were increased by 23% in lithium-treated subjects receiving meloxicam tablets. In other subjects, meloxicam did not alter warfarin pharmacokinetics.

NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices.

Pharmacokinetic and Pharmacodynamic Interactions
Meloxicam tablets therapy in patients receiving warfarin or similar agents, since these patients are at an increased risk of serious GI bleeding due to the synergistic effects of the 2 drugs. The effects of meloxicam tablets therapy in patients receiving warfarin or similar agents, since these patients are at an increased risk of serious GI bleeding due to the synergistic effects of the 2 drugs.

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The effects of meloxicam tablets therapy in patients receiving warfarin or similar agents, since these patients are at an increased risk of serious GI bleeding due to the synergistic effects of the 2 drugs.
For substantial overdose or severely symptomatic patients, activated charcoal may be administered.

Administration of activated charcoal is recommended for patients who present 1-2 hours after overdose.

Severe poisoning may result in hypertension, acute renal failure, hepatic failure, and death.

Risk of severe bleeding can occur. Fractures of the桡骨 and 脐骨 can be treated with the help of a surgeon, the dog's ability and safety of embolization, medical conditions, and patient's ability to control.

Two 12-week multicenter, double-blind, randomized trials were conducted in patients with RA to compare the efficacy and safety of meloxicam with placebo.

Table 2a depicts adverse events that occurred in ≥ 2% of the meloxicam treatment groups in a 12-week osteoarthritis placebo and/or active-controlled trials and 2363 of these patients were treated in ten placebo and/or active-controlled osteoarthritis trials.

Table 2b depicts adverse events that occurred in ≥ 2% of patients receiving meloxicam in 4 to 6 weeks and 6-month active-controlled osteoarthritis trials.

Table 2c depicts adverse events that occurred in ≥ 2% of patients receiving meloxicam in 15 daily doses and 15 mg daily doses.

Nursing Mothers

It is not known whether meloxicam is excreted in human milk. However, meloxicam was excreted in the milk of lactating rats following oral administration of the rats. meloxicam is a racemic mixture of two enantiomers.

OVERDOSAGE

Overdose is limited to experience with meloxicam overdose. Four cases have been reported to date.

A-CUTANEOUS AND MUCOUS MEMBRANE

The following is a list of adverse drug reactions occurring in < 2% of patients receiving meloxicam in placebo-controlled rheumatoid arthritis trials.

Table 3 depicts adverse events that occurred in ≥ 2% of patients receiving meloxicam in 4 to 6 weeks and 6-month active-controlled osteoarthritis trials.

Table 4 depicts adverse events that occurred in ≥ 2% of patients receiving meloxicam in 15 daily doses and 15 mg daily doses.
These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist about the side effects that you have. Other side effects include:

- Headache
- Swelling of the face or throat
- Chest pain
- Shortness of breath or trouble breathing
- Weakness in one part or side of your body
- Chest pain
- Stomach pain
- Nausea
- Vomiting
- Gas
- Constipation
- Stomach pain
- Swelling of the face or throat

Get emergency help right away if you have any of the following symptoms:

- Changes in facial expression
- Shakiness
- Changes in vision
- Changes in hearing
- Changes in speech

Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:

- Changes in facial expression
- Shakiness
- Changes in vision
- Changes in hearing
- Changes in speech

Other important side effects with NSAID medicines are:

- Abdominal pain
- Bloody or black stools
- Changes in urination
- Changes in bowel movements
- Decrease or increase in the amount of vaginal discharge
- Changes in stool
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Vicoprofen contains the same dose of ibuprofen as over-the-counter (OTC) NSAIDs, and is usually use for less than 10 days to treat pain. The OTC NSAID label warns that long term continuous use may increase the risk of heart attack or stroke.

Piroxicam
Feldene
Sulindac
Clinoril
Tolmetin, Tolectin, Tolectin DS, Tolectin 600

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Strides Arcolab Limited
Bangalore-560 076, India.

Manufactured for:
Apotex Corp.
Weston, Florida 33326

Revision: December 2009
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