Meloxicam Tablets, USP

FULL PRESCRIBING INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

The individual patient

Osteoarthritis (OA) (1.1)

Cardiovascular Risk

Initial U.S. Approval: 2000

and effectively. See full prescribing information for Meloxicam Tablets, USP.

HIGHLIGHTS OF PRESCRIBING INFORMATION

Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older (1.3)

Nonsteroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascula

●

1.2

1.3   Juvenile Rheumatoid Arthritis (JRA) Pauciarticular and Polyarticular Course

The 15 mg tablet is impressed with "100" mark on one side.

For the relief of the signs and symptoms of rheumatoid arthritis, the recommended startin

After observing the response to initial therapy with meloxicam, adjust the dose to suit a

Meloxicam tablets, USP is indicated for relief of the signs and symptoms of rheumatoi

l Studies (14.1)

Contraindications (4.2) and Warnings and Precautions (5.1)

Warnings and Precautions (5.1)
Meloxicam is a nonsteroidal anti-inflammatory drug (NSAID) that is used to treat the symptoms of osteoarthritis and rheumatoid arthritis. It is a compound that is structurally similar to aspirin and other NSAIDs, but with a longer duration of action and fewer side effects. Meloxicam is a pastel yellow solid, practically insoluble in water, with higher solubility observed in higher concentrations. The empirical formula is C₁₉H₁₇NO₄. It is available in 7.5 mg and 15 mg capsules as the free base.

**Pharmacokinetics**

- **Absorption:** Meloxicam is rapidly and completely absorbed following oral administration. The mean absolute bioavailability of meloxicam following a single oral administration of a 7.5 mg capsule is approximately 90%. The food effect on bioavailability was not significant. The mean maximum plasma concentration (Cmax) and the area under the curve (AUC) were increased by 21% in subjects receiving lithium doses ranging from 804 to 1072 mg/day.

- **Distribution:** The mean volume of distribution (Vss) of meloxicam is approximately 10 L. Meloxicam is extensively metabolized in the liver. The extent of hepatic extraction of meloxicam is approximately 90%. Meloxicam is almost completely (99%) bound to plasma proteins and is eliminated by the liver following biotransformation and by the biliary and urinary routes. The plasma half-life is 19.5 hours for females and 21 hours for males.

- **Elimination:** For single doses of 7.5 mg meloxicam, the mean elimination half-life was 19.5 hours for the female gender and 21 hours for the male gender. Administration of meloxicam capsules following a high fat breakfast (75 g of fat) resulted in a significant reduction of the AUC of meloxicam by 50%.

**Overdosage**

Patients should be managed with symptomatic and supportive care following an NSAID overdose. There is no specific antidote for the management of toxicity. In the event of an overdose, consult a poison control center (1-800-222-1222) or a hospital emergency department.

**Dose Forms**

- **Tablets:** Tablets are available in 7.5 mg and 15 mg strengths as the free base. Each 7.5 mg tablet is impressed with “5” mark on one side, and the 15 mg tablet is impressed with “10” mark on one side.

**Interactions**

- **Drug Interactions:** Meloxicam may affect the therapeutic response to warfarin and other drugs that are metabolized by the CYP2C9 isoenzyme. Therefore, patients who are on warfarin should be closely monitored for changes in INR and an increased risk of bleeding complications when a new medication is started. Meloxicam did not have a significant effect on the pharmacokinetics of single doses of methotrexate. Nevertheless, close monitoring of methotrexate plasma concentrations is recommended when methotrexate and meloxicam are used concurrently.

- **Carcinogenesis:** Meloxicam did not exhibit any significant local or systemic tumor-promoting activity in the mouse skininitiation/promotion bioassay or in the mouse colon initiation/promotion bioassay. Meloxicam did not induce the formation of tumors when given by oral administration in rats or mice. Meloxicam did not induce neoplastic transformation of human bronchial, bladder, and colon epithelial cells in vitro.

**Cautions**

- **Hepatic Impairment:** Meloxicam is metabolized in the liver. Meloxicam use should be avoided in patients with severe hepatic impairment. Consider dose reduction in patients with mild to moderate hepatic impairment.

**Contraindications**

- **Hypersensitivity**: Patients with a history of hypersensitivity to meloxicam or other NSAIDs should not use this medication.

**Warnings**

- **Thromboembolic Events:** NSAIDs, including meloxicam, may increase the risk of arterial and/or venous thromboembolic events. This risk may increase with duration of use and is greater at higher NSAID doses.

**Precautions**

- **Gastrointestinal Effects:** NSAIDs, including meloxicam, may increase the risk of gastrointestinal bleeding, ulceration, and perforation of the stomach and intestines, which can occur at any time during NSAID therapy and in any part of the GI tract, but is more likely to occur in older people with concomitant conditions that increase the risk of ulcers and bleeding, such as long-term use of corticosteroids or anticoagulants, concomitant use of aspirin, history of NSAID-associated gastrointestinal side effects, or other conditions (e.g., low body weight, heart failure, renal impairment, history of ulcer disease, surgical procedures involving the GI tract, history of diverticulitis, diverticulosis, or perforation).

**Adverse Reactions**

- **Gastrointestinal Effects:** The most common adverse reactions associated with the use of meloxicam are gastrointestinal in nature, including nausea, vomiting, diarrhea, dyspepsia, constipation, and flatulence. The frequency of these reactions is generally dose-related. Other digestive system reactions include epigastric distress, flatulence, dyspepsia, and eructation.

**Contraindications**

- **Hypersensitivity:** Patients with a history of hypersensitivity to meloxicam or other NSAIDs should not use this medication.

**Warnings**

- **Thromboembolic Events:** NSAIDs, including meloxicam, may increase the risk of arterial and/or venous thromboembolic events. This risk may increase with duration of use and is greater at higher NSAID doses.

**Precautions**

- **Gastrointestinal Effects:** NSAIDs, including meloxicam, may increase the risk of gastrointestinal bleeding, ulceration, and perforation of the stomach and intestines, which can occur at any time during NSAID therapy and in any part of the GI tract, but is more likely to occur in older people with concomitant conditions that increase the risk of ulcers and bleeding, such as long-term use of corticosteroids or anticoagulants, concomitant use of aspirin, history of NSAID-associated gastrointestinal side effects, or other conditions (e.g., low body weight, heart failure, renal impairment, history of ulcer disease, surgical procedures involving the GI tract, history of diverticulitis, diverticulosis, or perforation).

**Adverse Reactions**

- **Gastrointestinal Effects:** The most common adverse reactions associated with the use of meloxicam are gastrointestinal in nature, including nausea, vomiting, diarrhea, dyspepsia, constipation, and flatulence. The frequency of these reactions is generally dose-related. Other digestive system reactions include epigastric distress, flatulence, dyspepsia, and eructation.