Meloxicam Tablets, USP

INDICATIONS AND USAGE

Meloxicam Tablets, USP are indicated for the relief of signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), acute gouty arthritis, and as an analgesic and antipyretic in the management of mild to moderate pain in adults.

Meloxicam Tablets, USP are contraindicated in the following patients:

- Patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- Patients with previous serious skin reactions to Meloxicam Tablets, USP.
- Patients with previous thrombotic events.
- Patients with previous bleeding events.

DOSEAGE FORMS AND STRENGTHS

Meloxicam Tablets, USP: 7.5 mg and 15 mg (3)

CONTRAINDICATIONS

- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (4)
- Patients with previous serious skin reactions to Meloxicam Tablets, USP.
- Patients with previous thrombotic events.
- Patients with previous bleeding events.

WARNINGS AND PRECAUTIONS

1. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (1)

2. Osteoarthritis and Rheumatoid Arthritis

3. General Disorders and Administration Site Conditions

4. Gastrointestinal Disorders

5. Renal Toxicity

6. Heart Failure and Edema

7. Cardiovascular Thrombotic Events

8. Cardiovascular Risk Factors

9. Hyperkalemia

10. Hepatotoxicity

11. Female Reproduction

12. Drug Interactions

13. Use in Specific Populations

14. Clinical Laboratory Test Values

ADVERSE REACTIONS

The following adverse reactions have been identified during post approval use of Meloxicam Tablets, USP. These reactions may represent serious or life-threatening conditions.

15. Table 1: Adverse Reactions Occurring in 1% or More

16. Table 2: Adverse Events Occurring in 0.1% or More

17. Other Important Adverse Events

18. Overdose Therapy

FULL PRESCRIBING INFORMATION

For complete prescribing information, see Prescribing Information for Meloxicam Tablets, USP.

19. Full Prescribing Information

MELOXICAM TABLETS, USP

References

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http://www.fda.gov/medwatch

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**Mechanism of Action**

Meloxicam is a nonsteroidal anti-inflammatory drug (NSAID) that inhibits the synthesis of prostaglandins by selectively and irreversibly inhibiting cyclooxygenase-2 (COX-2). Prostaglandins are derived from arachidonic acid via the cyclooxygenase pathway, which is catalyzed by cyclooxygenase enzymes. COX-2 is the isoform that is specifically expressed in inflammation and cancer, while COX-1 is the constitutively expressed isoform in the healthy state.

**Drug Interactions**

Meloxicam is a potential inducer of cytochrome P450 3A4 (CYP3A4) enzymes, which could result in increased metabolism of drugs that are substrates for this enzyme system. Conversely, meloxicam can be affected by inhibitors of CYP3A4, such as clarithromycin and saquinavir.

**Dosage and Administration**

Meloxicam is available in 7.5 mg, 15 mg, and 22.5 mg capsules, and 15 mg tablets. It is usually taken by mouth once or twice daily with or without food, depending on the patient's condition.

**Contraindications**

Meloxicam is contraindicated in patients with a known hypersensitivity to meloxicam or to any other components of this product, and in patients with severe renal impairment.

**Warnings**

Meloxicam should be used with caution in patients with a history of gastrointestinal ulcer disease, and in those with a history of cardiovascular disease.

**Adverse Reactions**

Common adverse effects of meloxicam include abdominal pain, diarrhea, dizziness, headache, hypertension, and rash. More serious reactions may include gastrointestinal bleeding, cardiovascular events, and renal impairment.

**Pregnancy**

It is recommended that Meloxicam Tablets, USP be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Lactation**

Meloxicam is distributed in human milk and is not recommended for breastfeeding.

**Pediatric Use**

The safety and efficacy of Meloxicam Tablets, USP in pediatric patients under 2 years of age have not been established.

**Geriatric Use**

Older adults may be more susceptible to meloxicam's side effects, particularly those related to the gastrointestinal tract.

**Pregnancy/Breastfeeding**

There is no information available about the safety of Meloxicam Tablets, USP in women who are pregnant or breastfeeding.

**Clinical Trials**

In a clinical trial, meloxicam was found to be effective in reducing pain and inflammation, as well as improving function, in patients with osteoarthritis.

**References**

For more information, please refer to the full Prescribing Information for Meloxicam Tablets, USP.

**Medication Guide**

Please read the Medication Guide before starting treatment with Meloxicam Tablets, USP and save it for future reference.

**Further Resources**

For additional information, please visit the manufacturer's website or contact the customer service department.

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