Meloxicam tablets are non-steroidal anti-inflammatory drugs (NSAIDs) indicated for the relief of the signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis (OA).

**INDICATIONS AND USAGE**

Meloxicam tablets are indicated for relief of the signs and symptoms of RA and OA.

**Dosage and Administration**

- **RA:** The recommended starting and maintenance dose is 7.5 mg once daily.
- **OA:** The starting and maintenance dose is 7.5 mg once daily.
- **Juvenile Rheumatoid Arthritis (JRA):**
  - Pauciarticular and polyarticular course: Starting dose is 7.5 mg once daily. Increase to 15 mg once daily if necessary.
  - Systemic onset: Starting dose is 7.5 mg once daily. Increase to 15 mg once daily if necessary.

- **Contraindications:**
  - Meloxicam tablets are contraindicated in patients with a history of aspirin-sensitive asthma, urticaria, or angioedema.
  - Meloxicam tablets are contraindicated in patients with severe heart failure.
  - Meloxicam tablets are contraindicated in patients with a history of peptic ulcer disease and/or GI bleeding.
  - Meloxicam tablets are contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

- **Warnings and Precautions:**
  - Cardiovascular Thrombotic Events: Inform patients of warning signs and symptoms of cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. Avoid use of Meloxicam in patients with recent CABG surgery or with severe heart failure.
  - Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.
  - Hepatotoxicity: Discontinue if abnormal liver tests occur.

- **Drug Interactions:**
  - NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to assure diuretic effects.
  - Concomitant use with Meloxicam in elderly, volume-depleted, or those with renal impairment may increase risk of hypotension.

- **Full Prescribing Information:**
  - For detailed prescribing information, see full prescribing information for MELOXICAM TABLETS USP.
A 12-week multicenter, double-blind, randomized trial was conducted in patients with osteoarthritis of the knee. In this trial, the incidence of upper respiratory tract infection was 11.6% in the meloxicam group and 8.7% in the placebo group. This result suggests that meloxicam may have an advantage over placebo in reducing the incidence of upper respiratory tract infection in patients with osteoarthritis of the knee.

6.1 Clinical Trials Experience

The following adverse reactions are discussed in greater detail in other sections of the labeling:

5.11 Hematologic Toxicity

Meloxicam may cause allergic reactions including anaphylaxis and resulted in death. Seek emergency help if an anaphylactic reaction occurs.

5.8 Exacerbation of Asthma Related to Aspirin Sensitivity

Aspirin-sensitive patients may experience bronchospasm during meloxicam treatment. Use of a non-steroidal anti-inflammatory drug (NSAID) may cause exacerbation of asthma in patients with aspirin sensitivity.ältananti-inflammatory drug (NSAID) may cause exacerbation of asthma in patients with aspirin sensitivity.

5.10 Incomplete Renal Function and/or Intestinal Obstruction

Meloxicam is eliminated primarily by the kidney. An increase in meloxicam serum concentration may occur in patients with impaired renal function. Monitor serum creatinine and creatinine clearance in these patients. Adjust the dosage of meloxicam in patients with impaired renal function (see Table 1).

5.11 Hematologic Toxicity

Anemia has occurred in NSAID-treated patients. This may be due to occult or gross blood loss, fluid or electrolyte disturbance, or renal impairment. If anemia occurs, identify its cause before administering meloxicam.

5.12 Hepatic Toxicity

Severe hepatic reactions, including hepatic failure, have been reported with NSAIDs. Patients with preexisting liver disease are at risk for severe hepatic toxicity with the use of meloxicam. These patients may require more frequent liver function monitoring. Use meloxicam with caution in patients at risk for hepatic toxicity.

5.13 Pancreatitis

Pancreatitis has been reported with NSAIDs. Symptoms may include abdominal pain, nausea, and vomiting. If pancreatitis is suspected, discontinue meloxicam immediately and initiate appropriate treatment.

5.14 Fluid Retention and Edema

Fluid retention and edema have been reported with NSAIDs. Use meloxicam with caution in patients at risk for fluid retention and edema.

6.2 Lactation

This drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when meloxicam is administered to a nursing woman.

7.1 Basic Pharmacology

Meloxicam is a member of the COX-2 class of NSAIDs. It is a potent inhibitor of cyclooxygenase-2 (COX-2) and has a selectivity of approximately 70-fold greater for COX-2 than COX-1. Meloxicam does not inhibit platelet function and has a long duration of action.

7.2 Clinical Pharmacology

The bioavailability of meloxicam following oral administration is approximately 30%. The plasma concentration-time curve is characterized by a long terminal elimination half-life of approximately 17 hours. Meloxicam is extensively metabolized in the liver and approximately 95% of the dose is excreted in the urine, with less than 5% excreted in the feces.

7.3 Nonclinical Toxicology

Carcinogenicity studies

Meloxicam was not found to be carcinogenic in rats or mice when administered at high doses. However, long-term studies have not been conducted to evaluate carcinogenic potential for meloxicam in laboratory animals.

5 WARNINGS AND PRECAUTIONS

5.1 Boxed Warning

Avoid the use of meloxicam in patients with a recent MI unless the benefits are expected to outweigh the increased risk of cardiovascular thrombotic events. Use of meloxicam in patients who have experienced a MI within the last 10-14 days following CABG surgery is also contraindicated. Caution should be exercised when meloxicam is used concomitantly with other cardiovascular thrombotic medications. Meloxicam is not recommended for use in patients with a recent MI or CABG surgery.

5.2 Use in Specific Populations

5.2.1 Pregnancy

Meloxicam is contraindicated in women during pregnancy because harm to the fetus may occur. Use meloxicam only if the potential benefit justifies the potential risk to the fetus.

5.2.2 Nursing Mothers

Meloxicam is not recommended for use in nursing mothers because it may cause serious adverse reactions in the nursing infant.

5.2.3 Lactation

Meloxicam is not recommended for use in nursing mothers because it may cause serious adverse reactions in the nursing infant.

5.2.4 Children

Meloxicam is not recommended for use in children because its safety and effectiveness have not been established in this population.

5.2.5 Renal Impairment

Use meloxicam with caution in patients with renal impairment because it may cause increased serum creatinine levels.

5.2.6 Hepatic Impairment

Use meloxicam with caution in patients with hepatic impairment because it may cause increased serum bilirubin levels.

5.2.7 Congestive Heart Failure

Use meloxicam with caution in patients with congestive heart failure because it may cause increased fluid retention.

5.2.8 Edema

Use meloxicam with caution in patients with edema because it may cause increased fluid retention.

5.2.9 Cardiac Thrombotic Events

Avoid the use of meloxicam in patients with congestive heart failure, unstable angina, or recent MI unless the potential benefit justifies the risk. Use meloxicam with caution in patients with unstable angina or recent MI unless the potential benefit justifies the risk.

5.2.10 Hemorrhage

Use meloxicam with caution in patients with a history of peptic ulcer disease or hemorrhage because it may cause increased risk of hemorrhage.

5.2.11 Cerebrovascular Events

Use meloxicam with caution in patients with a history of stroke or TIA because it may cause increased risk of cerebrovascular events.

5.2.12 Peripheral Edema

Use meloxicam with caution in patients with peripheral edema because it may cause increased fluid retention.

5.2.13 Old Age

Use meloxicam with caution in patients over 75 years of age because they are at higher risk for adverse events.

5.2.14 Baseline Renal Function

Use meloxicam with caution in patients with baseline renal function less than 30 mL/min/1.73 m² because they are at higher risk for adverse events.

5.3 Contraindications

Meloxicam is contraindicated in patients with a recent MI or CABG surgery, in patients with severe asthma or other severe aspirin-induced anaphylaxis, and in patients with recent major surgery or trauma.

5.4 Warnings

Use meloxicam with caution in patients with a history of bronchial asthma, urticaria, or aspirin allergy because it may cause increased risk of asthma attacks.

5.5 Precautions

Use meloxicam with caution in patients with a history of gastrointestinal ulcers or bleeding because it may cause increased risk of gastrointestinal bleeding.

5.6 Adverse Reactions

The most common adverse reactions associated with meloxicam use are nasopharyngitis, headache, and upper respiratory tract infection. These reactions are typically mild to moderate in severity and are usually transient.

5.7 Drug Interactions

Meloxicam may increase the serum concentration of other drugs that are eliminated by hepatic metabolism or whose action is modulated by cytochrome P450. Avoid concomitant use of meloxicam with other drugs that are metabolized by the same enzymes.

5.8 Exacerbation of Asthma Related to Aspirin Sensitivity

NSAIDs, including meloxicam, can cause serious skin adverse reactions such as exfoliative dermatitis, fixed drug eruption, and urticaria. These reactions are usually reversible and may occur within days to weeks after initiating therapy. Discontinue meloxicam immediately if a severe skin reaction occurs.

5.9 Myocardial Infarction

NSAIDs, including meloxicam, can lead to new onset or worsening of preexisting hypertension, either of which may cause serious cardiovascular events.

5.10 Incomplete Renal Function and/or Intestinal Obstruction

Meloxicam is eliminated primarily by the kidney. An increase in meloxicam serum concentration may occur in patients with impaired renal function. Monitor serum creatinine and creatinine clearance in these patients. Adjust the dosage of meloxicam in patients with impaired renal function.

5.11 Hematologic Toxicity

Anemia has occurred in NSAID-treated patients. This may be due to occult or gross blood loss, fluid or electrolyte disturbance, or renal impairment. If anemia occurs, identify its cause before administering meloxicam.

5.12 Hepatic Toxicity

Severe hepatic reactions, including hepatic failure, have been reported with NSAIDs. Patients with preexisting liver disease are at risk for severe hepatic toxicity with the use of meloxicam. These patients may require more frequent liver function monitoring. Use meloxicam with caution in patients at risk for hepatic toxicity.

5.13 Pancreatitis

Pancreatitis has been reported with NSAIDs. Symptoms may include abdominal pain, nausea, and vomiting. If pancreatitis is suspected, discontinue meloxicam immediately and initiate appropriate treatment.

5.14 Fluid Retention and Edema

Fluid retention and edema have been reported with NSAIDs. Use meloxicam with caution in patients at risk for fluid retention and edema.

5.15 Cerebrovascular Events

Avoid the use of meloxicam in patients with a recent MI unless the benefits are expected to outweigh the increased risk of cerebrovascular events. Use of meloxicam in patients who have experienced a MI within the last 10-14 days following CABG surgery is also contraindicated. Caution should be exercised when meloxicam is used concomitantly with other cardiovascular thrombotic medications. Meloxicam is not recommended for use in patients with a recent MI or CABG surgery.

5.16 Hemorrhage

Use meloxicam with caution in patients with a history of peptic ulcer disease or hemorrhage because it may cause increased risk of hemorrhage.

5.17 Cerebrovascular Events

Avoid the use of meloxicam in patients with a recent MI unless the benefits are expected to outweigh the increased risk of cerebrovascular events. Use of meloxicam in patients who have experienced a MI within the last 10-14 days following CABG surgery is also contraindicated. Caution should be exercised when meloxicam is used concomitantly with other cardiovascular thrombotic medications. Meloxicam is not recommended for use in patients with a recent MI or CABG surgery.

5.18 Peripheral Edema

Use meloxicam with caution in patients with peripheral edema because it may cause increased fluid retention.

5.19 Old Age

Use meloxicam with caution in patients over 75 years of age because they are at higher risk for adverse events.

5.20 Baseline Renal Function

Use meloxicam with caution in patients with baseline renal function less than 30 mL/min/1.73 m² because they are at higher risk for adverse events.

5.21 Contraindications

Meloxicam is contraindicated in patients with a recent MI or CABG surgery, in patients with severe asthma or other severe aspirin-induced anaphylaxis, and in patients with recent major surgery or trauma.

5.22 Warnings

Use meloxicam with caution in patients with a history of bronchial asthma, urticaria, or aspirin allergy because it may cause increased risk of asthma attacks.

5.23 Precautions

Use meloxicam with caution in patients with a history of gastrointestinal ulcers or bleeding because it may cause increased risk of gastrointestinal bleeding.

5.24 Adverse Reactions

The most common adverse reactions associated with meloxicam use are nasopharyngitis, headache, and upper respiratory tract infection. These reactions are typically mild to moderate in severity and are usually transient.
In animal reproduction studies, embryofetal death was observed in rats and rabbits treated during the period of organogenesis with meloxicam at oral doses equivalent to 0.65- and 6.5-times the maximum expected human exposure. There are no adequate and well-controlled studies of meloxicam in pregnant women. Data from clinical trials in women and animal reproduction studies add to the evidence that proinflammatory cytokines play a significant role in the pathophysiology of rheumatoid arthritis and other chronic inflammatory conditions. In animal reproduction studies, meloxicam was not found to be teratogenic in rats and rabbits. In rats, however, treatment with meloxicam during the preimplantation period was shown to delay implantation and cause fetal losses at an oral dose of 30 mg/kg (approximately 0.65-times the maximum human exposure). In rabbits, the compound caused a significant increase in resorptions at an oral dose of 6.5 mg/kg (approximately 6.5-times the maximum human exposure).

In pregnant women, meloxicam is not a substitute for low-dose aspirin for cardiovascular protection. Meloxicam is not indicated for the prevention of cardiovascular thrombotic events. Meloxicam is not recommended for use in women during the second and third trimesters of pregnancy due to the risk of adverse reactions in the newborn and premature infants, especially respiratory depression, hypotension, and decreased cardiac output.

Serious fetal loss or maternal risk considerations may occur in women during the first trimester. Women who become pregnant during treatment with meloxicam should be apprised of the potential hazard to the fetus and should be carefully monitored.


**Risk Summary**

**8.1 Pregnancy**

Concomitant use of meloxicam and low-dose aspirin or analgesic doses of aspirin is not generally recommended because of the increased risk of bleeding [see Warnings and Precautions (5.2)].

**8.2 Lactation**

There is no information on the effects of meloxicam in breast milk. However, use of NSAIDs is not recommended in breastfeeding women because of the potential for serious adverse effects in nursing infants including serious renal toxicity.

**8.3 Children**

Clinical studies, as well as post-marketing observations, showed that NSAIDs reduced the natriuretic effect of loop diuretics (e.g., furosemide). Concomitant use of meloxicam and loop diuretics may lead to a reduction in the natriuretic effect of loop diuretics and to the development of oliguria and renal failure in diuretic-treated patients. NSAIDs reduce the protein-binding capacity of plasma, which may affect the protein-binding capacity of other plasma proteins (e.g., protein C, protein S, lipoproteins). The effect on the protein-binding capacity of other proteins is usually of little clinical importance. However, in patients with renal impairment, NSAIDs can displace meloxicam from plasma protein binding sites and thereby increase the risk of meloxicam toxicity. The concomitant use of meloxicam and diuretics in patients with renal impairment is not recommended.

**10.1 Post-Markeing Experience**

The adverse events most commonly reported with meloxicam (in descending order of frequency) are abdominal pain, vomiting, diarrhea, headache, and pyrexia. These adverse events are more common in patients with pauciarticular and polyarticular course juvenile rheumatoid arthritis (JRA) than in patients with other types of JRA. In a 12-week, placebo-controlled osteoarthritis trial, patients exposed to meloxicam with doses ranging from 0.125 to 0.375 mg/kg per day in three clinical trials.

**Table 1a** Depicts adverse events that occurred in ≥2% of the meloxicam treatment groups in a 12-week, placebo-controlled osteoarthritis trial. The adverse events most commonly reported with meloxicam (in descending order of frequency) are abdominal pain, vomiting, diarrhea, headache, and pyrexia. These adverse events are more common in patients with pauciarticular and polyarticular course juvenile rheumatoid arthritis (JRA) than in patients with other types of JRA. In a 12-week, placebo-controlled osteoarthritis trial, patients exposed to meloxicam with doses ranging from 0.125 to 0.375 mg/kg per day in three clinical trials.

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**Table 1b** Depicts adverse events that occurred in ≥2% of the meloxicam treatment groups in a 12-week, placebo-controlled osteoarthritis trial. The adverse events most commonly reported with meloxicam (in descending order of frequency) are abdominal pain, vomiting, diarrhea, headache, and pyrexia. These adverse events are more common in patients with pauciarticular and polyarticular course juvenile rheumatoid arthritis (JRA) than in patients with other types of JRA. In a 12-week, placebo-controlled osteoarthritis trial, patients exposed to meloxicam with doses ranging from 0.125 to 0.375 mg/kg per day in three clinical trials.

**Table 1c** Depicts adverse events that occurred in ≥2% of the meloxicam treatment groups in a 12-week, placebo-controlled osteoarthritis trial. The adverse events most commonly reported with meloxicam (in descending order of frequency) are abdominal pain, vomiting, diarrhea, headache, and pyrexia. These adverse events are more common in patients with pauciarticular and polyarticular course juvenile rheumatoid arthritis (JRA) than in patients with other types of JRA. In a 12-week, placebo-controlled osteoarthritis trial, patients exposed to meloxicam with doses ranging from 0.125 to 0.375 mg/kg per day in three clinical trials.
Meloxicam is extensively metabolized in the liver. Meloxicam metabolites include 5'-carboxy and 5'-hydroxymethyl metabolites, while unchanged meloxicam is excreted in urine and feces. The extent of the urinary excretion was confirmed for unlabeled multiple 7.5 mg doses: 0.5%, 6%, and 13% of the dose were found in urine in the form of meloxicam, and the 5'-hydroxymethyl metabolite was found in urine and feces. Only traces of the unchanged parent compound are excreted in the urine (0.2%) and feces (1.6%). The extent of the urinary excretion was confirmed for unlabeled multiple 7.5 mg doses: 0.5%, 6%, and 13% of the dose were found in urine in the form of meloxicam, and the 5'-hydroxymethyl metabolite was found in urine and feces. Only traces of the unchanged parent compound are excreted in the urine (0.2%) and feces (1.6%).

**Metabolism**

Meloxicam's metabolic profile is rich in its capacity to form metabolites, which are found in both urine and feces. The significant contribution of hepatic metabolism is evident in the formation of both unchanged meloxicam and its metabolites. The primary metabolic pathway involves the CYP2C9-mediated oxidation of an intermediate to form the 5'-carboxy metabolite. This metabolite is further conjugated with glucuronic acid, resulting in a water-soluble metabolite that is excreted in the urine.

**Elimination**

The terminal elimination phase of meloxicam is characterized by a narrow therapeutic index, with a substantial margin of safety. Following oral administration, meloxicam is rapidly absorbed, with peak plasma concentrations typically achieved between 5 and 6 hours. The drug exhibits linear pharmacokinetics over a wide dose range. The free fraction of meloxicam in synovial fluid is approximately 2.5 times higher than in plasma, due to the lower albumin concentration in synovial fluid. This difference may contribute to its therapeutic advantage in conditions such as rheumatoid arthritis.

**Pharmacokinetic Parameters**

The pharmacokinetic parameters of meloxicam are presented in Table 3, which includes data from single (0.25 mg/kg) dose administration and after achieving steady state (0.375 mg/kg/day) in geriatric patients and young adults.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Geriatric Patients</th>
<th>Young Adults</th>
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</thead>
<tbody>
<tr>
<td>Tmax (h)</td>
<td>5-6</td>
<td>5-6</td>
</tr>
<tr>
<td>Cmax (μg/mL)</td>
<td>3.2 (24)</td>
<td>4.8 (24)</td>
</tr>
<tr>
<td>Css (μg/mL)</td>
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<td>1.80 (24)</td>
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<tr>
<td>Vd/F</td>
<td>1.5 (12)</td>
<td>1.3 (12)</td>
</tr>
<tr>
<td>Cl/F</td>
<td>0.08 (12)</td>
<td>0.09 (12)</td>
</tr>
<tr>
<td>t1/2 (h)</td>
<td>16 (29)</td>
<td>15 (42)</td>
</tr>
</tbody>
</table>

**Absorption**

Absorption of meloxicam is rapid and complete following oral administration. The bioavailability of meloxicam is high, and it reaches peak plasma concentrations within 5-6 hours after oral dosing. The absence of first-pass metabolism and the lack of significant enterohepatic recycling contribute to its high bioavailability.

**Distribution**

The apparent volume of distribution (Vd/F) of meloxicam in the elderly is slightly reduced compared to young adults, indicating that the drug is distributed extensively throughout the body. The distribution of meloxicam is not significantly influenced by age, and the free fraction in synovial fluid is 2.5 times higher than in plasma, due to the lower albumin concentration in synovial fluid.

**Excretion**

The extent of drug excretion is primarily via the renal route, with minimal amounts excreted in the feces. Following oral dosing, over 90% of the radioactivity is excreted in the urine, indicating a high degree of renal clearance. The extent of protein binding is minimal, with only a small fraction (5% to 10%) of the dose free in plasma.

**Protein Binding**

The protein binding of meloxicam is low, with only 5% to 10% of the dose free in plasma. This high degree of protein binding may contribute to its long half-life and slow elimination.

**Special Populations**

**Geriatric Use**

Geriatric patients, especially those with age-related renal impairment, may require a dosage adjustment to ensure safety and efficacy. The elderly population may have a smaller body weight and reduced muscle mass, which can affect the metabolism and elimination of meloxicam.

**Infertility**

Meloxicam has been associated with an increased risk of infertility in some studies, possibly due to its inhibitory effect on prostaglandin synthesis, which is involved in ovulation. However, these findings are not consistent across all studies, and the relationship between meloxicam use and infertility is not well-established.

**Overdosage**

**Overdosage Treatment**

Overdosage with meloxicam can result in a range of adverse effects, including gastrointestinal bleeding, hypotension, and renal failure. The treatment of meloxicam overdose involves supportive care, hydration, and monitoring of vital signs. In severe cases, hemodialysis may be considered to remove the drug from the circulation.
If you take any other medicine for a condition for which your doctor has prescribed NSAIDs, or if you take over-the-counter NSAIDs for a different condition, let your doctor know. Do not take NSAIDs for a different condition without first talking with your healthcare provider. Taking other medicines at the same time as NSAIDs can cause serious side effects.

You should not take NSAIDs after 29 weeks of pregnancy. If you become pregnant while taking NSAIDs, stop taking them and call your doctor right away.

Before you start using any new medicine, talk to your doctor or pharmacist. It is especially important to check with your doctor or pharmacist if:

- you are allergic to any medicine.
- you have asthma.
- you have high blood pressure.
- you have liver or kidney problems.
- you have blood problems.
- you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- you have had heart disease.
- you have had a heart attack or stroke.
- you have uncontrolled high blood pressure.
- you have bleeding problems.
- you have advanced liver disease.
- you have a bleeding disorder.
- you have used methotrexate or gold.
- you have had surgery in the past 2 months.
- you have had an organ transplant.
- you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- you have had heart disease.
- you have had a heart attack or stroke.
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- you have used methotrexate or gold.
- you have had surgery in the past 2 months.
- you have had an organ transplant.
- you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- you have had heart disease.
- you have had a heart attack or stroke.
- you have uncontrolled high blood pressure.
- you have bleeding problems.
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