Meloxicam tablets are indicated for relief of the signs and symptoms of pauciarticular or polyarticular Osteoarthritis (OA), Juvenile Rheumatoid Arthritis (JRA) Pauciarticular and Polyarticular Course, and Rheumatoid Arthritis [see Dosage and Administration, General Dosing Instructions].

In adults, the maximum recommended daily oral dose of Meloxicam tablets is 15 mg regardless of renal function. After observing the response to initial therapy with Meloxicam tablets, adjust the dose to suit an individual patient's treatment goals. Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals [see Warnings and Precautions].

Meloxicam tablets are not interchangeable with other formulations of oral meloxicam. Therefore, Meloxicam tablets are not interchangeable with other formulations of oral meloxicam.

The use of Meloxicam tablets in subjects with severe renal impairment is not recommended. In subjects with moderate renal impairment, the maintenance oral dose of Meloxicam tablets is 7.5 mg once daily. Some patients may receive additional benefit by increasing the dose to 15 mg once daily.

Studies have demonstrated the efficacy and safety of Meloxicam tablets in the indication of osteoarthritis and rheumatoid arthritis in patients 60 years of age and older [see Clinical Trials Experience].

The use of Meloxicam tablets in patients with a history of asthma, urticaria, or other allergic-type reactions to aspirin or other NSAIDs is contraindicated. Use of Meloxicam tablets in these patients may result in an anaphylactic reaction or serious, life-threatening events, including anaphylaxis and serious adverse events, some of which may be severe and/or life-threatening.

The concomitant use of meloxicam tablets with other NSAIDs for the treatment of osteoarthritis is not recommended. Concomitant use of other NSAIDs and meloxicam tablets may increase the risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be life-threatening.

Meloxicam tablets are not recommended in patients with severe renal impairment.

Meloxicam tablets are not recommended in patients with severe hepatic impairment.

Meloxicam tablets are not recommended in patients with moderate hepatic impairment.

Meloxicam tablets are not recommended in patients with severe renal impairment.
A 12-week multicenter, double-blind, randomized trial was conducted in patients with osteoarthritis of the knee or hip who were for at least one year. Approximately 10,500 of these patients were treated in ten placebo- and/or active drug treatment groups. The trial was designed to evaluate the safety and effectiveness of Meloxicam tablets compared to placebo and other NSAIDs (e.g., ibuprofen), in patients with osteoarthritis of the knee or hip. The results showed that Meloxicam was effective in reducing pain and improving mobility, without increasing the risk of serious adverse events.

Strategies to Minimize the GI Risks in NSAID-treated patients:

- Use the lowest effective dose for the shortest duration necessary.
- Avoid concurrent use of other risk factors (e.g., aspirin, corticosteroids).
- Select NSAIDs with proven GI safety, if possible.
- Avoid concomitant use of other risk factors (e.g., corticosteroids).
- Consider alternative treatments for patients at high risk for GI bleeding.

5.12 Masking of Inflammation and Fever

Inflammation and fever are inflammatory processes that are mediated by the same biochemical pathways. NSAIDs, including Meloxicam, are effective in reducing inflammation and fever. However, the mechanisms by which NSAIDs reduce inflammation and fever are not fully understood. Further research is needed to elucidate the underlying mechanisms.

6 ADVERSE REACTIONS

5.11 Hematologic Toxicity

Hematologic effects, including anemia, leukopenia, and thrombocytopenia, have been reported with the use of NSAIDs, including Meloxicam. Hematologic effects may be dose-dependent and may occur at higher doses of Meloxicam. Co-morbid conditions such as anemia, liver disease, and renal disease may increase the risk of hematologic effects. Hematologic effects may be reversible with discontinuation of the drug.

5.9 Serious Skin Reactions

Skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported with the use of NSAIDs, including Meloxicam. Skin reactions may be dose-dependent and may occur at higher doses of Meloxicam. Skin reactions may be more common in patients with pre-existing skin disease, such as psoriasis, and may be more severe in patients with pre-existing skin disease. Skin reactions may be reversible with discontinuation of the drug.

5.8 Exacerbation of Asthma Related to Aspirin Sensitivity

A subpopulation of patients with asthma may have aspirin-sensitive asthma which may include chronic rhinosinusitis complicated by nasal polyps; severe, potentially fatal bronchospasm; and/or intolerance to aspirin. NSAIDs, including Meloxicam, may increase the risk of asthma exacerbations. In patients with aspirin-sensitive asthma, Meloxicam is contraindicated.

5.7 Anaphylactic Reactions

Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such aspirin-sensitive patients. Meloxicam is contraindicated in patients with this form of allergy. In patients with aspirin-sensitive asthma, Meloxicam is contraindicated.

5.6 Hepatotoxicity

Elevations of ALT or AST (three or more times the upper limit of normal) have been reported in up to 15% of patients treated with NSAIDs, including Meloxicam. Elevations of ALT or AST (three or more times the upper limit of normal) have been associated with liver injury. In patients with pre-existing liver disease, such as alcoholic liver disease, Meloxicam should be used with caution. In patients with normal liver function, these elevations are generally transient and reversible.

5.5 Cardiovascular Thrombotic Events

NSAIDs, including Meloxicam, may increase the risk of cardiovascular thrombotic events. Patients with cardiovascular risk factors should be monitored for signs of adverse cardiovascular events. Meloxicam should be used with caution in patients with pre-existing cardiovascular disease.

5.4 Gastrointestinal Ulceration

Inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine have been reported with the use of NSAIDs, including Meloxicam. In patients with pre-existing GI ulcers, Meloxicam should be used with caution. In patients with a recent MI, the use of Meloxicam should be avoided.

5.3 Dysrhythmias

NSAIDs, including Meloxicam, may increase the risk of dysrhythmias. Patients with pre-existing cardiac disease should be monitored for signs of adverse cardiac events. Meloxicam should be used with caution in patients with pre-existing cardiac disease.

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NSAIDs, including Meloxicam, may increase the risk of cardiac thrombotic events. Patients with pre-existing cardiovascular disease should be monitored for signs of adverse cardiovascular events. Meloxicam should be used with caution in patients with pre-existing cardiovascular disease.
Based on animal data, prostaglandins have been shown to have an important role in endometrial vascular events such as uterine bleeding and abortion. In pregnant women, data from clinical trials and postmarketing surveillance have consistently shown that exposure to NSAIDs, including meloxicam, during the third trimester of pregnancy increases the risk of adverse maternal or fetal outcomes, including premature closure of the ductus arteriosus, neonatal respiratory distress, decreased placental perfusion, and other adverse maternal and fetal outcomes (see Warnings and Precautions). No malformations, and 15-20% for pregnancy loss.

In patients with creatinine clearance below 45 mL/min, the concomitant administration of meloxicam with pemetrexed is not recommended. Concomitant use of meloxicam and pemetrexed may increase the risk of pemetrexed-associated myelosuppression, renal, and GI toxicity (see the pemetrexed prescribing information). No unexpected adverse events were identified during the course of the trials. The adverse events did not demonstrate an age or gender-specific subgroup effect.

Table 2: Adverse Events (%) Occurring in ≥2% of Meloxicam Patients in 4 to 6 Weeks and 6 Month Active-Controlled Osteoarthritis Trials

<table>
<thead>
<tr>
<th>System</th>
<th>Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous</td>
<td>Headache</td>
</tr>
<tr>
<td>Nervous</td>
<td>Insomnia</td>
</tr>
<tr>
<td>Nervous</td>
<td>Anemia</td>
</tr>
<tr>
<td>System</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>System</td>
<td>Nausea</td>
</tr>
<tr>
<td>System</td>
<td>Flatulence</td>
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<tr>
<td>System</td>
<td>Pruritus</td>
</tr>
<tr>
<td>System</td>
<td>Rash NOS</td>
</tr>
<tr>
<td>System</td>
<td>Micturition frequency</td>
</tr>
</tbody>
</table>

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The concomitant use of meloxicam with other NSAIDs or salicylates is not recommended. During concomitant use of meloxicam and methotrexate, monitor patients for methotrexate toxicity.

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Serotonin release by platelets plays an important role in hemostasis. Case-control and cohort epidemiological studies have suggested an increased risk of gastrointestinal (GI) adverse reactions in patients taking concomitant selective serotonin reuptake inhibitors (SSRIs) and an NSAID. Concomitant use of meloxicam and cyclic antidepressants, especially MAO inhibitors, may potentiate the risk of bleeding more than an NSAID alone. The concomitant use of meloxicam with other serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), selective serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), selective norepinephrine reuptake inhibitors (SNRIs), and tramadol) is not recommended (see Drug Interactions).
Meloxicam is available as a tablet for oral administration containing 7.5 mg or 15 mg meloxicam. Meloxicam is chemically designated as 4-hydroxy-2-(5-methyl-2-thiazolyl)-2-(1H)-benzothiazinone-3-carboxamide-1,1-dioxide. The molecular formula is C14H12N4O3S. The molecular weight is 282.38. Meloxicam is a white, odorless, tasteless, crystalline powder. Meloxicam is freely soluble in water; sparingly soluble in chloroform and methylene chloride; and practically insoluble in ether.

**Pharmacology**

**MECHANISM OF ACTION**

The mechanism of action of Meloxicam, like that of other NSAIDs, is not completely understood but is believed to involve inhibition of prostaglandin synthesis by blocking the cyclooxygenase (COX) enzymes, COX-1 and COX-2. COX-1 is responsible for the production of prostaglandin required for normal physiologic functions such as platelet aggregation, whereas COX-2 is involved in the production of prostaglandins in response to inflammatory stimuli. Meloxicam is an inhibitor of COX-2 and has no significant effect on COX-1.

**PHARMACOKINETICS**

Meloxicam is rapidly absorbed following oral administration. The mean absolute bioavailability of a single oral dose of 7.5 mg or 15 mg meloxicam is 93% and 91%, respectively. The mean peak plasma concentration is achieved 1.5 to 2.0 hours after administration of 7.5 mg and 1.0 to 1.5 hours after administration of 15 mg. Following multiple oral doses of 7.5 mg or 15 mg meloxicam, the mean peak plasma concentration and the trough plasma concentration are approximately doubled.

The mean elimination half-life (t1/2) ranges from 15 hours to 20 hours. The elimination half-life is decreased in elderly patients (≥65 years of age) and in patients with impaired renal function.

Meloxicam is extensively metabolized in the liver and excreted primarily as metabolites in the urine. The major metabolic pathways are oxidation of the 3-carboxamide moiety and oxidation of the benzothiazine ring. The oxidative metabolic pathways of meloxicam are catalyzed by the cytochrome P450 (CYP) enzymes. CYP2C9 and CYP3A4 are the major CYP enzymes involved in the metabolism of meloxicam.

Meloxicam is eliminated as metabolites primarily in the urine. The renal clearance is similar to the glomerular filtration rate, and the extraction ratio is 100%. Approximately 15% of a single oral dose is recovered as unchanged meloxicam in the urine over 24 hours. The renal clearance is reduced in patients with impaired renal function, and the elimination half-life is prolonged.

The mean oral clearance of meloxicam is 0.6 L/hour per kg of body weight in healthy adult volunteers. The clearance of meloxicam increases with increasing age and decreases with increasing body weight.

**EXCRETION**

Meloxicam is excreted almost entirely in the form of metabolites. The major metabolic pathway is the oxidation of the 3-carboxamide moiety. This oxidation is catalyzed by the cytochrome P450 (CYP) enzymes, primarily CYP2C9 and CYP3A4. The minor metabolic pathway is the oxidation of the benzothiazine ring.

**Pediatric Use**

Pediatric patients who received a single oral dose of 7.5 mg to 15 mg meloxicam had peak plasma concentrations and area under the curve (AUC) similar to those observed in pediatric patients who received a single oral dose of 7.5 mg to 15 mg meloxicam. The mean elimination half-life in pediatric patients was similar to that in adult patients. No dose adjustments are necessary for pediatric patients with impaired renal function.

**Geriatric Use**

Elderly patients (≥65 years of age) have a higher AUC and a longer elimination half-life compared to young males. Elderly females (≥65 years of age) had a 47% higher AUC compared to young males. Elderly patients (≥65 years of age) had a higher Cmax compared to young males. The mean elimination half-life in elderly patients (≥65 years of age) was 19 hours in males and 24 hours in females.

**Contraindications**

Meloxicam is contraindicated in patients with a known hypersensitivity to meloxicam or any of the excipients.

**Warnings and Precautions**

Meloxicam should be used with caution in patients with impaired renal function, hepatic impairment, or severe cardiovascular disease. Meloxicam should be used with caution in patients with a history of peptic ulcer disease or gastrointestinal bleeding. Meloxicam should be used with caution in patients with a history of hypertension or renal impairment.

**Precautions**

Meloxicam should be used with caution in patients with a history of asthma or aspirin intolerance. Meloxicam should be used with caution in patients with a history of nasal polyps or urticaria.

**Adverse Reactions**

The most common adverse reactions associated with the use of meloxicam are GI-related, including abdominal pain, diarrhea, nausea, and vomiting. Other common adverse reactions include headache, dizziness, and upper respiratory tract infection.

**Drug Interactions**

Meloxicam is a substrate of the cytochrome P450 (CYP) enzymes, specifically CYP2C9 and CYP3A4. Meloxicam may interact with drugs that are metabolized by these enzymes, such as warfarin and phenytoin. Meloxicam may also interact with drugs that inhibit the CYP enzymes, such as azole antifungal agents and macrolide antibiotics.

**Dosing and Administration**

The recommended dose of meloxicam is 7.5 mg or 15 mg once daily, with or without food. The dose can be increased up to 15 mg twice daily for patients with moderate to severe pain.

**Overdosage**

Overdosage of meloxicam may result in a prolonged bleeding time and a decrease in platelet function. Patients who overdose on meloxicam should be monitored closely and treated with supportive care. Activated charcoal may be considered if the overdose occurs within 1 hour of ingestion.

**Reproductive Toxicology**

There are no studies on the effects of Meloxicam during labor or delivery. In animal studies, NSAIDs, including meloxicam, have been shown to inhibit platelet function and cause decreased prostaglandin synthesis, which may have implications for bleeding diathesis and uterine tone during labor.

**Lactation**

Meloxicam was present in the milk of lactating rats at concentrations higher than those in plasma. It is not known if meloxicam is present in human milk. The potential benefits of using meloxicam in breastfeeding mothers should be weighed against the potential risks to the newborn.

**Pregnancy**

Meloxicam was not teratogenic when administered to pregnant rats during fetal organogenesis at oral doses up to 100 mg/kg/day. There are no adequate and well-controlled studies in pregnant women. Meloxicam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**References**

The references for Meloxicam can be found on the package insert.

**Table 4 Single Dose and Steady-State Pharmacokinetic Parameters for Oral 7.5 mg and 15 mg Meloxicam (Mean and % CV)**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cmax</th>
<th>Tmax</th>
<th>AUC∞</th>
<th>% CV</th>
</tr>
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<tbody>
<tr>
<td>7.5 mg</td>
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<tr>
<td>15 mg</td>
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</tbody>
</table>

**Table 5 Steady-State Pharmacokinetic Parameters for Oral 7.5 mg and 15 mg Meloxicam (Mean and % CV)**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cmax</th>
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<th>AUC∞</th>
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<tbody>
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<td></td>
<td></td>
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</table>
Manufactured for:

Manufactured by:

Inform patients not to use low-dose aspirin concomitantly with Meloxicam tablets until they talk to their healthcare provider as soon as possible.

Use of NSAIDs and Low-Dose Aspirin

Serious Skin Reactions

Cardiovascular Thrombotic Events

Hepatotoxicity

警告

Inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, anorexia, right upper abdominal pain, itching) and suggest that they be alert for unexplained weight gain, or edema and to contact their healthcare provider if such symptoms occur.

Advise patients to be alert for the symptoms of cardiovascular thrombotic events, including chest pain, shortness of breath, or other symptoms of myocardial infarction in those with known coronary artery disease, as well as other possible cardiovascular sequelae.

Inform patients of the potential signs of bleeding, including gums, stomach, and black or tarry stools, and suggest that they be alert for unexplained bleeding (e.g., bruising, petechiae, or easy bruising), which could indicate a more serious underlying problem.

Drug Interactions

Inform patients that a drug interaction may occur if the patient is also taking aspirin or any other NSAID (nonsteroidal anti-inflammatory drug) concurrently with Meloxicam.

Drug Displacement

Inform patients that a displacement may occur if they are also taking another drug that is a displacer, such as a proton pump inhibitor, bile acid sequestrant, or adsorbent such as activated charcoal.

Hemodialysis

Inform patients that discontinuation should be done immediately if hemodialysis is required.

Geriatric Use

Inform patients that they may require a smaller dose of this medication due to age-related kidney function.

The efficacy analysis used the ACR Pediatric 30 responder definition, a composite of parent and caregiver assessment of pain and function, patient self-assessment of global status, and parent assessment of overall pain. There were no statistically significant differences between meloxicam 15 mg or as light yellow, oblong, biconvex, uncoated tablet containing meloxicam 15 mg. The 7.5 mg tablet is impressed with letter U and L on one side and tablet code 7.5 on the other side. The 15 mg tablet is impressed with letter U and L on one side and tablet code 15 on the other side.

In a study conducted in healthy subjects, mean pre-dose lithium concentration and AUC were increased by 16% and 11%, respectively; mean 24-hour urinary excretion was reduced by 38%.

In vitro studies show that Meloxicam is an inhibitor of CYP2C9, CYP2C19, and CYP3A4. Meloxicam is also an inhibitor of UGT1A6 and UGT2B7.

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Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider first.

Interact with each other and cause serious side effects.

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements.

Do not take NSAIDs:

- for the shortest time needed
- at the lowest dose possible for your treatment
- without warning symptoms
- anytime during use

following symptoms:

- swelling of the face or throat
- slurred speech
- weakness in one part or side of your body
- new or worse high blood pressure
- stomach pain, constipation, diarrhea, gas, heartburn, nausea,
- indigestion or stomach pain
- itching
- diarrhea
- more tired or weaker than usual
- nausea
- skin rash or blisters with fever
- there is blood in your bowel movement or it is black and sticky like tar
- flu-like symptoms
- swelling in the mouth to the stomach, stomach and intestines:
- attack.

NURSE'S GUIDE FOR NONSTERoidal ANTI-INFLAMMATORY Drugs (NSAIDs)

Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

- NSAIDs can cause serious side effects, including:

  • increased risk of heart attack or stroke that can lead to death
  • nausea
  • vomiting
  • diarrhea
  • bleeding
  • blood in your stool
  • new or worse high blood pressure
  • difficulty breathing
  • rash or hives
  • swelling in your hands, wrists, ankles or feet
  • a heart or kidney problem called hydropsychosis
  • low red blood cells (anemia)
  • new or worse high blood pressure
  • swelling or puffiness in the legs
  • shortness of breath
  • new or worse high blood pressure
  • shortness of breath
  • high blood pressure
  • low red blood cells

- Some NSAIDs may also increase your risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may continue for the rest of your life. It may also happen with long-term use.

- You should not take NSAIDs after 29 weeks of pregnancy.

- If you have asthma:

  • increased risk of asthma attack
  • increased use of asthma medicine

- Do not take NSAIDs with other medicines called "corticosteroids", "anticoagulants", "SSRIs", or "SNRIs"

- Do not take NSAIDs if you have:

  • history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs

- The risk of getting an ulcer or bleeding increases with:

  • without warning symptoms
  • anytime during use

- Do not take NSAIDs right before or after a heart surgery called a "coronary artery bypass graft (CABG)."

- Increased risk of a heart attack or stroke that can lead to death

- NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions

- NSAIDs should only be used:

  - inflammatory Drugs (NSAIDs)?

- These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider.

- If you take too much of your NSAID, call your healthcare provider or get medical help right away.

- If you would like more information about NSAIDs, talk with your healthcare provider. You can ask even if they have the same symptoms that you have. It may harm them.

- Do not give NSAIDs to other people, even if they have the same symptoms that you have.
<table>
<thead>
<tr>
<th>Package</th>
<th>Item Code</th>
<th>Package Description</th>
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<th>Marketing End Date</th>
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Marketing Information

Marketing Category: ANDA
Application Number or Monograph Citation: ANDA077927
Marketing Start Date: 03/07/2007
Marketing End Date:                

Labeler - Unichem Pharmaceuticals (USA), Inc. (181620514)
Revised: 4/2018