Meloxicam is contraindicated in the following patients:

Pharmacology (2.4 Juvenile Rheumatoid Arthritis (JRA) Pauciarticular and Polyarticular Course

The maintenance oral dose of meloxicam is 7.5 mg once daily. Some patients may receive additional benefit by increasing the dose above 7.5 mg in clinical trials.

For the treatment of juvenile rheumatoid arthritis, the recommended oral dose of meloxicam is 7.5 mg once daily. Some patients may receive additional benefit by increasing the dose above 7.5 mg in clinical trials.

2.2 Osteoarthritis

Populations (1.1 Osteoarthritis (OA)

Individual patient treatment goals should be considered when choosing the appropriate initial dose of meloxicam. Use the lowest effective dosage for the shortest duration consistent with individual patient goals of treatment and may diminish the antihypertensive effect of these drugs. Monitor blood pressure.

2.1 General Dosing Instructions

1.1 Osteoarthritis (OA)

Meloxicam tablets should not be used in children who weigh <60 kg. The dose above 7.5 mg in clinical trials.

For the treatment of juvenile rheumatoid arthritis, the recommended oral dose of meloxicam is 7.5 mg once daily. Some patients may receive additional benefit by increasing the dose above 7.5 mg in clinical trials.

2.3 Rheumatoid Arthritis

The recommended starting and oral dose of meloxicam is 7.5 mg once daily. Some patients may receive additional benefit by increasing the dose above 7.5 mg in clinical trials.
Table 1b depicts adverse events that occurred in ≥2% of the meloxicam treatment groups in two 12-placebo- and active-controlled osteoarthritis trials. Meloxicam at these doses was administered to 312 patients for at least 6 months and to 2363 of these patients were treated in ten placebo- and/or active-controlled osteoarthritis trials. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug. The duration of exposure to the drug in the clinical trials is generally much shorter than exposure in daily life, and the conditions of patients in clinical trials cannot be compared to those in the community.

Adverse reaction rates may also vary for several reasons, such as differences in patient selection, differences in patient treatment, and variations in how reactions are assessed and reported. Differences in patient selection may result from differences in how patients are selected for clinical trials, the diseases included in the study, and the study endpoints selected.

Other factors that may contribute to differences in adverse reaction rates include differences in the duration of exposure to the drug, differences in the dose and route of administration, and differences in the extent of follow-up. These factors can all influence the rate at which adverse reactions are reported and the likelihood that a reaction will be observed.

While the frequency of adverse reactions may vary among different studies, the overall pattern of reactions observed in clinical trials is generally consistent with the pattern observed in clinical practice. However, there are some exceptions to this pattern, and the frequency of adverse reactions may be higher or lower than expected in a particular patient population.

5.10 Premature Closure of Fetal Ductus Arteriosus

Monitoring for Premature Closure of Fetal Ductus Arteriosus

Premature closure of the ductus arteriosus is unusual but can occur. If a patient treated with meloxicam has signs or symptoms of this condition, the drug should be discontinued and the patient should be evaluated for the possibility of closure of the ductus arteriosus. If closure occurs, the patient may require medical intervention to prevent serious complications.

5.11 Hematologic Toxicity

Hematologic Toxicity

5.12 Anaphylaxis

Anaphylaxis

5.13 Pneumonitis

Pneumonitis

5.14 Drug Interactions

Drug Interactions

5.15 Other Interventions

Other Interventions

5.16 Laboratory Tests

Laboratory Tests

5.17 Recommended Monitoring

Recommended Monitoring

5.18 Use in Pregnancy

Use in Pregnancy

5.19 Use in the Elderly

Use in the Elderly

5.20 General Precautions

General Precautions

5.21 Contraindications

Contraindications

5.22 Warnings and Precautions

Warnings and Precautions

5.23 Unlabeled Use

Unlabeled Use

5.24 Adverse Reactions

Adverse Reactions

5.25 Overdose

Overdose

5.26 Post-Marketing Surveillance

Post-Marketing Surveillance

5.27 Information for Patients

Information for Patients

5.28 Product Information

Product Information

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Collaborators

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Available Formulations

5.32 Other Information

Other Information

5.33 Table of Contents

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5.34 Conclusions

Conclusions

5.35 Acknowledgments

Acknowledgments

5.36 References

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In rats and rabbits, embryolethality occurred at oral meloxicam doses equivalent to 0.08- and 2.6-times the maximum recommended human dose (MRHD) respectively. Administration of meloxicam to pregnant rabbits throughout embryogenesis produced an increased incidence of septal heart defects and an increased incidence of stillbirth.

Based on animal data, prostaglandins have been shown to have an important role in endometrial vascular permeability and maintenance of pregnancy. Meloxicam is a potent inhibitor of prostaglandin synthesis. The effects of meloxicam on the human fetal outcome are unknown.

Meloxicam was not teratogenic when administered to pregnant rats during fetal organogenesis at oral doses equivalent to 0.65- and 6.5-times the maximum recommended human dose (MRHD). In pre- and post-natal reproduction studies, there was an increased incidence of dystocia, delayed parturition, and decreased offspring survival at 0.08-times MRHD of meloxicam. No increase in any of these parameters was observed at 2.6-times MRHD.

In a study of patients who received meloxicam during the first trimester of pregnancy, the incidence of second and third trimester spontaneous abortions was not increased in comparison to the background rate of 2-4% for major congenital malformations. However,, the available data do not reliably estimate their frequency or establish a causal relationship to drug exposure. Decisions about the use of any drug in pregnant women must be individualized for each patient.

Table 2: Meloxicam (mg) (N=12) of Reproduction Studies in Rats when Administered to Pregnant Animals

<table>
<thead>
<tr>
<th>Species</th>
<th>Dose (mg/kg)</th>
<th>Duration (days)</th>
<th>Route</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.08</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
<tr>
<td>Rabbit</td>
<td>0.65</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
<tr>
<td>Rabbit</td>
<td>6.50</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
<tr>
<td>Rabbit</td>
<td>2.60</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 3: Adverse Events (%) Occurring in ≥ 2% of Meloxicam Patients in 4 to 6 Weeks and Month 6

<table>
<thead>
<tr>
<th>Body System</th>
<th>4 to 6 Weeks (%)</th>
<th>Month 6 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3.2</td>
<td>3.2</td>
</tr>
<tr>
<td>Urinary</td>
<td>2.7</td>
<td>2.7</td>
</tr>
<tr>
<td>Metabolic</td>
<td>1.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Hematologic</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Nervous</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>2.7</td>
<td>2.7</td>
</tr>
<tr>
<td>Appendages</td>
<td>469</td>
<td>469</td>
</tr>
</tbody>
</table>

Warnings and Precautions

Lactation

There are no data available on whether meloxicam is present in human milk, or on the effects on nursing infants. Because many drugs are excreted in human milk, caution should be exercised when meloxicam is administered to a nursing woman.

Table 1: Meloxicam (mg) Impact on Reproduction and Development

<table>
<thead>
<tr>
<th>Species</th>
<th>Dose (mg/kg)</th>
<th>Duration (days)</th>
<th>Route</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.08</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
<tr>
<td>Rabbit</td>
<td>0.08</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 6: Meloxicam (mg) Impact on Reproduction and Development

<table>
<thead>
<tr>
<th>Species</th>
<th>Dose (mg/kg)</th>
<th>Duration (days)</th>
<th>Route</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.08</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
<tr>
<td>Rabbit</td>
<td>0.08</td>
<td>20</td>
<td>PO</td>
<td>-</td>
</tr>
</tbody>
</table>

Adverse Reactions

Adverse events that occurred with meloxicam in ≥ 2% of patients treated short-term (4 to 6 weeks) and long-term (6 months) are described in Table 3. Some adverse reactions were not observed in clinical trials because patients were not exposed for long periods of time at 10 mg daily (in controlled clinical trials) and 20 mg daily (in uncontrolled clinical trials).

NSAIDs have produced elevations in plasma lithium levels and reductions in renal lithium clearance. The mean minimum lithium level increased by approximately 20%. This effect has been attributed to NSAID inhibition of renal prostaglandin synthesis.

The administration of meloxicam with salicylates may diminish the antihypertensive effect of angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), or beta-blockers (including propranolol).

Meloxicam may interfere with hemostasis and coagulation as manifested by decreases in clotting times.

The administration of meloxicam with salicylates may diminish the antihypertensive effect of angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), or beta-blockers (including propranolol).

The administration of meloxicam with cyclosporine may diminish the antihypertensive effect of angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), or beta-blockers (including propranolol).

During concomitant use of meloxicam and pemetrexed, in patients with renal impairment whose creatinine clearance ranges from 45 to 79 mL/min, monitor for myelosuppression, renal and GI toxicity.

In patients with creatinine clearance below 45 mL/min, the concomitant administration of meloxicam with pemetrexed is not recommended.
Meloxicam is a rapidly absorbed oral anti-inflammatory and analgesic agent that is indicated for the relief of pain and inflammation associated with osteoarthritis, rheumatoid arthritis, primary dysmenorrhea, dental surgery, postoperative pain, and gout. It is a nonsteroidal anti-inflammatory drug (NSAID) and is available in multiple formulations, including tablets, capsules, and oral suspension. The molecular formula of meloxicam is C_{17}H_{17}ClN_{3}O_{2}, with a molecular weight of 351.4. Its empirical formula is C_{17}H_{17}ClN_{3}O_{2}.

**Pharmacokinetics**

Following oral dosing, meloxicam is rapidly absorbed and reaches peak plasma concentrations within 30 minutes to 3 hours. The absolute bioavailability of meloxicam is approximately 90%. The plasma half-life of meloxicam is approximately 14 hours, with a terminal phase half-life of 21 hours. Meloxicam is extensively metabolized in the liver, primarily by cytochrome P450 isoenzymes CYP2C9 and CYP3A4. The major metabolite is 5'-hydroxymethyl meloxicam, which is excreted in urine. Meloxicam is eliminated primarily by renal excretion, with approximately 90% of the dose excreted in urine and feces. The renal clearance of meloxicam is greater than the intrinsic renal clearance, indicating that its elimination is significantly influenced by its renal excretion.
Who should not take NSAIDs?

What are NSAIDs?

The risk of getting an ulcer or bleeding increases with

Avoid taking NSAIDs after a recent heart attack, unless your healthcare provider tells you to.

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Inform patients not to use low-dose aspirin concomitantly with meloxicam until they talk to their

Use of NSAIDs and Low-Dose Aspirin

NSAIDs may be present in "over the counter" medications for treatment of colds, fever, or insomnia.

Salsalate) is not recommended due to the increased risk of gastrointestinal toxicity, and little or no

Fetal Toxicity

may be associated with a reversible delay in ovulation [see Warnings and Precautions (5.4)].

Inform pregnant women to avoid use of meloxicam and other NSAIDs starting at 30 weeks gestation

Healthcare providers should counsel pregnant women of the potential risks associated with NSAID use.

Anaphylactic Reactions

Advise patients to stop meloxicam immediately if they develop any type of rash and to contact their

Warnings and Precautions (5.1)

instruct patients to seek immediate emergency help if these occur [see Warnings and Precautions (5.7)].

Advise patients to be alert for the symptoms of congestive heart failure including shortness of breath,

Inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy,

Advise patients to report symptoms of ulcerations and bleeding, including epigastric pain, dyspepsia,

Advise patients to be alert for the symptoms of cardiovascular thrombotic events, including chest pain,

Prescribers should not order an order of these patients to treat at a dose of greater than 20 mg/day

Prescription Dispensed.

17 PATIENT COUNSELING INFORMATION

Dispense tablets in a tight container.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Keep meloxicam tablets in

Meloxicam tablets, USP 7.5 mg are available as follows:

NDC 69097-159-12                  Bottles of 500
NDC 69097-159-07                  Bottles of 100
NDC 69097-158-15                  Bottles of 1000

14.2 Juvenile Rheumatoid Arthritis (JRA) Pauciarticular and Polyarticular Course

Meloxicam 7.5 mg and 15 mg daily showed significant improvement in the primary endpoint compared

The proportion of responders were similar in all three groups in both studies, and no

investigator assessments, counts of active joints and joints with limited range of motion, and erythrocyte

the other incorporated a titration after 4 weeks to doses of 0.25 mg/kg/day and 0.375 mg/kg/day (22.5 mg

dosing began at 10 mg/kg/day. One study used these doses throughout the 12-week dosing period, while

Both studies included three arms: naproxen and two doses of meloxicam. In both studies, meloxicam

course Juvenile Rheumatoid Arthritis in patients 2 years of age and older was evaluated in two 12-

was compared to placebo. The primary endpoint in this study was the ACR20 response rate, a

trial.

these trials, the efficacy of meloxicam, in doses of 7.5 mg/day and 15 mg/day, was comparable to

questionnaire addressing pain, function, and stiffness). Patients on meloxicam 7.5 mg daily and

patient global assessment, patient pain assessment, and total WOMAC score (a self-administered

Meloxicam did not impair male and female fertility in rats at oral doses up to 9 mg/kg/day in males and 5

human lymphocytes and an

Carcinogenesis

Methotrexate:

Lithium:

Digoxin:

Cimetidine:

significant drug interactions of NSAIDs with aspirin [see Warnings and Precautions (5.1)].

of meloxicam. The clinical significance of this interaction is not known. See Table 3 for clinically

(20% of subjects). The mean AUC was similar among all three treatments.

Micronucleus Test

A study in 13 rheumatoid arthritis (RA) patients evaluated the effects of multiple doses of

in vitro

A study in 17 RA patients comparing doses of meloxicam 7.5 mg, 15 mg, and 20 mg evaluated the effect

on prothrombin time in a group of 10 healthy male subjects. There were no clinically significant

average anticoagulant effect of warfarin as determined by prothrombin time. However, one subject

binding drug interaction between digoxin and meloxicam.

Digoxin:

Cimetidine:

No significant drug interactions of meloxicam and aspirin were observed in a group of 12 healthy

In vitro

No significant drug interactions of meloxicam and ibuprofen were observed in a group of 12 healthy

In vitro

Concomitant administration of 200 mg cimetidine four times daily did not alter the single-

Free fraction. Hemodialysis did not lower the total drug concentration in plasma; therefore, additional

doses are not necessary after hemodialysis. Meloxicam is not dialyzable [see Drug Interactions (7.4)].

8.7 Adverse Reactions

Osteoporosis is a significant adverse reaction associated with the use of meloxicam.

7.2 Effects on Laboratory Tests

8.3 Post Marketing Experience

8.1 Overdose

Meloxicam tablets 7.5 mg/ml, 15 mg/ml are indicated for the treatment of osteoarthritis, rheumatoid

oral NSAIDs. The risk of adverse events increases with increasing doses of NSAIDs and the duration of

older age

○ older age

○ taking medicines called "corticosteroids", "anticoagulants", "SSRIs", or "SNRIs"

anytime during use

This risk may happen early in


### Revised: 9/2019

**Cipla**

**100 Tablets**

**WITH MEDICATION GUIDE**

**PHARMACIST: PLEASE DISPENSE**

**15 mg Tablets, USP**

**Meloxicam**

**NDC 69097-159-07      Rx ONLY**

---

**Revised: 2/2017**

9100 S. Dadeland Blvd., Suite 1500
Miami, FL 33156

Cipla USA, Inc.

Manufactured for:

Kurkumbh, India

Manufactured by:

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### General information about the safe and effective use of NSAIDs

NSAIDs can cause serious side effects, including:

- **Kidney problems including kidney failure**
- **Liver problems including liver failure**
- **New or worse high blood pressure**
- **Severe skin reactions**
- **Low red blood cells (anemia)**
- **Severe allergic reactions**

### Other side effects of NSAIDs

Other side effects of NSAIDs include:

- **Diabetes**
- **Diabetes due to lack of insulin**
- **Diabetes due to decreased blood flow to the pancreas**

### What is the most important information I should know about medicines called Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)?

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

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

- **Severe skin reactions**
- **New or worse high blood pressure**
- **Severe chest pain**
- **Severe allergic reactions**

### Other information about NSAIDs:

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. The General information about the safe and effective use of NSAIDs may not be all the information you need about your medicine. Talk with your healthcare provider if you have questions about your medicine.

---

### Packaging Information

**Package Description**

- **ORAL HUMAN PRESCRIPTION DRUG**

**Route of Administration**

- **ORAL**

**Ingredient Information**

- **MELOXICAM**
  - **Active Ingredient/Active Moiety**
    - **MELOXICAM**
  - **Inactive Ingredients**
    - **SODIUM STEARATE**
    - **CELLULOSE, MICROCRYSTALLINE**

**Product Information**

- **Strength**
  - **7.5 mg**

**Marketing Information**

- **Application Number or Monograph Citation**
  - **NDC:69097-158**

**Marketing Start Date**

- **07/19/2006**

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### Imprint Code

- **CIPLA;159**

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### Data Source

- **Cipla USA Inc.**

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### Note

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