Meloxicam Tablets, USP:

Meloxicam Tablets are non-steroidal anti-inflammatory drug indicated for:

- Relief of the signs and symptoms of rheumatoid arthritis (see Dosage and Administration)
- Relief of the signs and symptoms of osteoarthritis (OA) (see Dosage and Administration)

**INDICATIONS AND USAGE**

Meloxicam Tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis (see Dosage and Administration).

**DOSAGE AND ADMINISTRATION**

For the relief of the signs and symptoms of rheumatoid arthritis, the recommended starting and 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.

**CONTRAINDICATIONS**

- Meloxicam is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- Meloxicam is contraindicated in the setting of recent myocardial infarction and unstable angina pectoris.
- Meloxicam is contraindicated in patients with a history of aspirin-inducedasthma, anaphylactic reactions, or urticaria.

**WARNINGS AND PRECAUTIONS**

- Cardiovascular events: Concomitant use of meloxicam with diuretics, ACE inhibitors, or NSAIDs may increase the risk of cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- Gastrointestinal events: Concomitant use of meloxicam with aspirin may increase the risk of serious GI events, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Patients with a history of peptic ulcer disease and/or GI bleeding are at greater risk for these events.
- Hypertension: In elderly, volume-depleted patients, or those with low blood pressure, meloxicam may diminish the antihypertensive effect of these drugs.
- Diuretics: NSAIDs can reduce the natriuretic effect of furosemide and thiazide diuretics. Monitor patients for signs of volume retention and hypotension.

**ADVERSE REACTIONS**

Common adverse reactions include:

- Gastrointestinal: Nausea, vomiting, diarrhea, and constipation
- Cardiovascular: Hypertension
- Respiratory: Upper respiratory tract infections
- CNS: Headache
- Hematologic: Anemia

**DOSE FORMS AND STRENGTHS**

Meloxicam tablets, for oral use.

**REFERENCES**

- Zydus Pharmaceuticals (USA) Inc. (2016).

**FULL PRESCRIBING INFORMATION**

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

**FULL PRESCRIBING INFORMATION: CONTENTS**

1. INDICATIONS AND USAGE
2. DOSAGE AND ADMINISTRATION
3. CONTRAINDICATIONS
4. WARNINGS AND PRECAUTIONS
5. ADVERSE REACTIONS
6. USE IN SPECIFIC POPULATIONS
7. DOSAGE FORMS AND STRENGTHS
8. REFERENCES
Week placebo-controlled rheumatoid arthritis trials. Meloxicam to compare the efficacy and safety of meloxicam with placebo.

Two 12-week multicenter, double-blind, randomized trials were conducted in patients with active-controlled rheumatoid arthritis trials. Gastrointestinal (GI) adverse events were the most frequent causes of discontinuation. At 15 mg/day, meloxicam was associated with fewer discontinuations due to adverse events than placebo. Patients treated with meloxicam 7.5 mg/day, 3505 OA patients and 1351 RA patients treated with meloxicam 15 mg/day. Meloxicam at these doses was administered to 661 patients for at least 6 months.

ADVERSE REACTIONS

5.12 Masking of Inflammation and Fever

NSAIDs, including meloxicam, may cause a decrease in the symptoms of inflammation and fever. This may occur in the absence of clinically significant underlying disease. Patients with a history of asthma should be monitored for signs of exacerbation of bronchial asthma symptoms or bronchospastism following NSAID initiation. Patients with history of aspirin-induced asthma may have additional bronchospastic reactions to NSAIDs, including meloxicam. In the absence of clinically significant underlying disease, NSAIDs, including meloxicam, may cause a decrease in the symptoms of inflammation and fever.

5.9 Serious Skin Reactions

Serious skin reactions, including Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), or adverse reactions of similar severity, may be fatal. These events may also occur in patients without a history of a previous reaction to an NSAID. SJS and TEN may occur at any time during treatment with NSAIDs. Some patients may have had a previous reaction with a different NSAID before the onset of a serious skin reaction with meloxicam.

Seek emergency help if an anaphylactic reaction occurs. Warnings and Precautions (see ). Patients with a history of asthma are at increased risk of serious skin reactions with NSAIDs. Patients with a history of asthma should be monitored for signs of exacerbation of bronchial asthma symptoms or bronchospastism following NSAID initiation. Patients with a history of aspirin-induced asthma may have additional bronchospastic reactions to NSAIDs, including meloxicam.

5.5 Heart Failure and Edema

Monitor blood pressure (BP) during the initiation of NSAID treatment and throughout the course of therapy. NSAIDs, including meloxicam, may cause an increase in BP. This may be more prominent in patients with renal insufficiency, heart failure, or hypertension. Heart failure, dehydration, or hypovolemia during use of meloxicam increase the risk of adverse events related to meloxicam use. NSAIDs, including meloxicam, may cause an increase in BP. This may be more prominent in patients with renal insufficiency, heart failure, or hypertension.

Table 5-12 shows adverse reactions summarized in the Usage in Specific Populations (see ). It is important to note that an atrial fibrillation (AF) event was reported after the first year post-MI in a patient treated with meloxicam. This patient was started on meloxicam within 24 hours of the MI event and was taking an aspirin product at the time of event. In addition, this patient had a prior MI, and his medical history included hypertension, hyperlipidemia, and diabetes mellitus. He was receiving treatment with a beta blocker at the time of the AF event.

Use of meloxicam may blunt the CV effects of several therapeutic agents used to treat these medical conditions (e.g., diuretics, ACE inhibitors, or angiotensin receptor blockers). These agents may be more likely to cause fluid retention, sodium retention, and cardiovascular volume expansion in patients with impaired renal function, dehydration, or hypovolemia. Use of meloxicam may blunt the CV effects of several therapeutic agents used to treat these medical conditions (e.g., diuretics, ACE inhibitors, or angiotensin receptor blockers). These agents may be more likely to cause fluid retention, sodium retention, and cardiovascular volume expansion.

5.6 Renal Function Impairment

If meloxicam is used in patients with advanced renal disease, monitor patients for signs of worsening renal function. If meloxicam is used in patients with advanced renal disease, monitor patients for signs of worsening renal function.

No information is available from controlled clinical studies regarding the use of meloxicam in patients with chronic renal insufficiency. In patients with normal renal function, these patients may be at risk for adverse renal effects of meloxicam. In patients with normal renal function, these patients may be at risk for adverse renal effects of meloxicam. In patients with normal renal function, these patients may be at risk for adverse renal effects of meloxicam. In patients with normal renal function, these patients may be at risk for adverse renal effects of meloxicam.

5.8 Drug Interactions

Upon initiation of meloxicam therapy, patients who are taking warfarin should be monitored for changes in anticoagulation parameters. Use of meloxicam may alter the effects of warfarin in patients with impaired renal function, dehydration, or hypovolemia. Use of meloxicam may alter the effects of warfarin in patients with impaired renal function, dehydration, or hypovolemia. Use of meloxicam may alter the effects of warfarin in patients with impaired renal function, dehydration, or hypovolemia.

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5.2 Status Post Coronary Artery Bypass Graft (CABG) Surgery

Two large, controlled clinical trials of a COX-2 selective NSAID, celecoxib, have shown an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, in patients with a recent MI. Patients with a recent MI treated with meloxicam may be at increased risk of serious cardiovascular events. Patients with a recent MI treated with meloxicam may be at increased risk of serious cardiovascular events.

Blood pressure control is important in the management of patients with cardiovascular disease, and dosage recommendations for meloxicam should be consistent with other antihypertensive medications. Patients with a recent MI treated with meloxicam may be at increased risk of serious cardiovascular events.

Table 5-12 shows adverse reactions summarized in the Usage in Specific Populations (see ). It is important to note that an atrial fibrillation (AF) event was reported after the first year post-MI in a patient treated with meloxicam. This patient was started on meloxicam within 24 hours of the MI event and was taking an aspirin product at the time of event. In addition, this patient had a prior MI, and his medical history included hypertension, hyperlipidemia, and diabetes mellitus. He was receiving treatment with a beta blocker at the time of the AF event.

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pregnant women starting at 30 weeks of gestation (third trimester) may increase the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs, including meloxicam, in late pregnancy.

Use of NSAIDs, including meloxicam, during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus, which may cause fetal distress. Meloxicam is not recommended for use after the second trimester of pregnancy.

Precautions

6.2 Postmarketing Experience

Rash was reported in seven (<2%) patients receiving meloxicam. No unexpected adverse reactions were reported in these trials. Adverse reactions were monitored in all patients who received meloxicam during phase 3 trials involving approximately 16,200 patients.

The adverse events that occurred with meloxicam in ≥2% of patients treated short-term (4 to 6 weeks) and long-term (6 months) are listed in Table 1 and Table 2. Adverse events were more common with meloxicam than with placebo. The most common adverse events were dyspeptic signs and symptoms, abdominal pain NOS, gastrointestinal irritation, upper respiratory tract infections-pathogen unspecified, joint related signs and symptoms, arthralgia, arthralgia aggravated, joint pain aggravated, joint swelling, flatulence, and dyspepsia.

Table 1: Adverse Events (%) Occurring in ≥ 2% of Meloxicam Patients in a 12-Week Active-Controlled Rheumatoid Arthritis Placebo-Controlled Trials

<table>
<thead>
<tr>
<th>System</th>
<th>Placebo (%)</th>
<th>Meloxicam (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accident household</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain NOS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nervous tract infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematologic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>2.7</td>
<td>5.7</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2.8</td>
<td>6.7</td>
</tr>
<tr>
<td>Accident household</td>
<td>2.2</td>
<td>4.6</td>
</tr>
<tr>
<td>Abdominal pain NOS</td>
<td>3.0</td>
<td>4.8</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Upper respiratory tract</td>
<td>1.3</td>
<td>1.6</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Nervous tract infection</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Hematologic</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Potential effects on pregnancy and laktation

Meloxicam is not recommended for use after the second trimester of pregnancy. Meloxicam is excreted in human milk, and there are reports of adverse effects on infants.

Clinical Pharmacology

Meloxicam is a selective COX-2 inhibitor and is metabolized in the liver by CYP2C9 to its active metabolites. The metabolites are mainly excreted in urine.

4.4.1 Drug Interactions

Meloxicam is not metabolized by CYP2C19 or CYP3A4, making it less likely to interact with other drugs that are metabolized by these enzymes.

Table 3: Clinically Significant Drug Interactions with Meloxicam

<table>
<thead>
<tr>
<th>Drug</th>
<th>Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td></td>
</tr>
<tr>
<td>Salicylates</td>
<td></td>
</tr>
<tr>
<td>NSAIDs</td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td></td>
</tr>
<tr>
<td>Pemetrexed</td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td></td>
</tr>
<tr>
<td>Warfarin</td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td></td>
</tr>
<tr>
<td>Interfere</td>
<td></td>
</tr>
<tr>
<td>Epilepsy medications</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant use of meloxicam with other NSAIDs or salicylates is not recommended. During concomitant use of meloxicam and cyclosporine, monitor patients for signs of worsening renal function. Concomitant use of meloxicam and cyclosporine may increase cyclosporine's nephrotoxicity.

During concomitant use of meloxicam and methotrexate, monitor patients for methotrexate toxicity. Meloxicam and anticoagulants such as warfarin have a synergistic effect on bleeding. The concomitant use of meloxicam and anticoagulants have an increased risk of serious bleeding compared to the use of either drug alone.

Other combined use with anticoagulants and corticosteroids may increase bleeding risk. The concomitant use of meloxicam and corticosteroids increases the risk of gastrointestinal ulcers.
Meloxicam, USP is a pale yellow powder, practically insoluble in water, slightly soluble in acetone, 2-methyl-1,2-benzothiazine-3-carboxamide-1,1-dioxide. The molecular weight is 216.2. Meloxicam has the following structural formula.

Fourteen percent of a single oral dose of radio-labeled meloxicam was excreted unchanged in urine and 54% in feces. Over 90% of an oral radiolabeled dose of meloxicam was metabolized via oxidative dealkylation to 5'-hydroxymethyl meloxicam. The major metabolite is highly hydrophilic and is excreted in the urine; only about 2% of the dose is excreted in feces. Other minor metabolites include the 5'-carboxy metabolite and some oxidation products of the 5'-hydroxymethyl metabolite. These metabolites are excreted in both urine and feces.

12.3 Pharmacokinetics

Meloxicam is rapidly absorbed from the GI tract. Absorption was complete by 8 hours postdose and not significantly affected by food. Peak plasma concentrations were reached by Day 5. A second meloxicam concentration peak occurs around 12 to 14 days after the initial peak. In fasted conditions, indicating a prolonged drug absorption. With multiple dosing, steady-state pharmacokinetics of meloxicam capsules were dose-proportional over the range of 7.5 mg to 15 mg.

Table 1: Single and Multiple Pharmacokinetic Parameters for oral meloxicam (Mean and SD)

<table>
<thead>
<tr>
<th>Dose (mg)</th>
<th>Single</th>
<th>Multiple</th>
<th>Steady-State</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.5</td>
<td>11.0</td>
<td>11.0</td>
<td>11.0</td>
</tr>
<tr>
<td>15</td>
<td>15.0</td>
<td>15.0</td>
<td>15.0</td>
</tr>
<tr>
<td>30</td>
<td>30.0</td>
<td>30.0</td>
<td>30.0</td>
</tr>
</tbody>
</table>

Dosage adjustment

No dose adjustment is necessary in patients with mild to moderate renal impairment. Patients with severe renal impairment or those undergoing hemodialysis (serum creatinine: 1.5 to 12 mg/dL) should receive a significantly lower initial dose (i.e., 7.5 mg or 15 mg). In patients with severely impaired renal function (serum creatinine: >12 mg/dL), therapy should not be initiated, and meloxicam must be discontinued if renal function deteriorates during therapy.

In patients with hepatic insufficiency, the safety and effectiveness of meloxicam have not been established. However, based on the generally accepted principles of pharmacokinetics and pharmacodynamics, a reduced initial dosage (i.e., 7.5 mg) and careful monitoring of the patient are recommended before use in such patients.

12.4 Metabolism

Metabolism of meloxicam occurs primarily in the liver via CYP2C9-mediated oxidation (formation of 5'-hydroxymethyl metabolite) and subsequent conjugation with sulfate and glucuronic acid. A second liver pathway involves hydroxylation at the 2-methyl group to form 2-methyl-1,2-benzothiazine-3-carboxylic acid. These metabolites are highly water-soluble and are excreted in the urine. Neither parent compound nor any of its metabolites are secreted into human breast milk.

12.5 Excretion

The major route of elimination of meloxicam is via the urine (94% of a single oral dose) and feces (3.5% of a single oral dose). Following a single intravenous dose (5 mg), approximately 45% of the dose is excreted in urine and 1% of the dose is excreted in feces. No meloxicam-related inorganic ions are excreted in the urine. Meloxicam is not eliminated by the kidneys in patients with normal renal function. However, in patients with reduced renal function, the elimination of meloxicam is prolonged. The elimination half-life of meloxicam increases with increasing renal impairment, and longer dosing intervals may be considered in such patients.

12.6 Special Populations

12.6.1 Elderly

In healthy elderly volunteers, the elimination half-life of meloxicam was increased by 30% relative to young healthy men. Age-related changes in renal function may result in a longer elimination half-life and prolonged effect in elderly patients.

12.6.2 Children

Meloxicam is generally well tolerated in children aged 6 months to 12 years. The plasma levels of meloxicam in children aged 1 to 7 years were approximately 25-30% lower than those observed in adults. The biopharmaceutical properties of meloxicam oral suspension are similar in children and adults.

12.6.3 Labor and Delivery

There are no adequate and well-controlled studies in pregnant women. The use of meloxicam during pregnancy should be avoided, especially during the third trimester, due to the potential risk of fetal harm. Meloxicam should be given to pregnant women only if the potential benefit justifies the potential risk to the fetus.

13.1 Pregnancy

Meloxicam should not be administered to pregnant women. If meloxicam is given to a woman who is or may become pregnant, she should be apprised of the potential risk to the fetus. The use of meloxicam during pregnancy should be avoided, especially during the third trimester, due to the potential risk of fetal harm.

13.1.1 Animal Data

In animal studies, meloxicam caused a delay in parturition at oral doses up to 60 mg/kg/day and 15 mg/kg/day, respectively (71- and 19-fold greater than the MRHD of meloxicam based on BSA). In dogs, meloxicam at an oral dose of 15 mg/kg/day resulted in a delay in parturition.

13.2 Lactation

It is unknown whether meloxicam is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when meloxicam is administered to a nursing mother.

13.3 Effects in Women

In animal studies, meloxicam resulted in an increase in the number of stillbirths in pregnant rabbits treated orally with meloxicam at a dose of 30 mg/kg/day (6.5-fold greater than the MRHD of meloxicam based on BSA). Meloxicam also increased the incidence of septal defects of the heart at an oral dose of 60 mg/kg/day (78-fold greater than the MRHD of meloxicam based on BSA). In rats, the incidence of pre- and post-implantation loss was increased at oral doses of 60 mg/kg/day (67-fold greater than the MRHD of meloxicam based on BSA) and 100 mg/kg/day (98-fold greater than the MRHD of meloxicam based on BSA).

13.4 Effects in Men

In animal studies, meloxicam inhibited spermatogenesis in a dose-dependent manner, indicating a decrease in fertility in male rats treated orally with meloxicam at doses up to 30 mg/kg/day (13-fold greater than the MRHD of meloxicam based on BSA).

15.1 Milk-

There are no human 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 mother.

15.2 Labor

There are no studies on the effects of meloxicam during labor or delivery. In animal studies, administration of prostaglandin synthesis inhibitors, such as meloxicam, resulted in increased pre- and post-implantation loss, decreased blastocyst implantation, and decreased decidualization. In animal studies, administration of meloxicam resulted in increased pre- and post-implantation loss, decreased blastocyst implantation, and decreased decidualization.

15.3 Teratogenicity

Animal studies have shown that meloxicam administered during organogenesis at oral doses up to 30 mg/kg/day (13-fold greater than the MRHD of meloxicam based on BSA) had no effect on fertility or on the development of the embryo or fetus. In rats, at an oral dose of 60 mg/kg/day (78-fold greater than the MRHD of meloxicam based on BSA), there was a dose-dependent prolongation of parturition due to inhibition of prostaglandin synthesis.

15.4 Breastfeeding

There are no adequate and well-controlled studies in women who are nursing at the time they begin taking meloxicam. Because many drugs are excreted in human milk, caution should be exercised when meloxicam is administered to lactating women.

15.5 Infertility Females

There are no studies in women treated with meloxicam that have shown a delay in ovulation. Consider whether to discontinue the medication when a woman is planning to become pregnant.

15.6 Infertility Males

Meloxicam has caused a delay in parturition at oral doses up to 60 mg/kg/day and 15 mg/kg/day, respectively (71- and 19-fold greater than the MRHD of meloxicam based on BSA). The administration of meloxicam to male rats at oral doses up to 15 mg/kg/day resulted in a delay in parturition.

16.1 Nursing Mothers

Meloxicam is not recommended for use in nursing women due to the potential for serious adverse reactions in the nursing infant. If meloxicam is given to a woman who is or may become pregnant, she should be apprised of the potential risk to the fetus. The use of meloxicam during pregnancy should be avoided, especially during the third trimester, due to the potential risk of fetal harm.

16.2 Labor and Delivery

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17.1 Disposition of Human Milk

The purchase of this product may be subject to state or local law. If this is not the product you request, please contact your account executive.

17.2 Refrigeration

The purchase of this product may be subject to state or local law. If this is not the product you request, please contact your account executive.

17.3 Storage

The purchase of this product may be subject to state or local law. If this is not the product you request, please contact your account executive.

17.4 Disposal

The purchase of this product may be subject to state or local law. If this is not the product you request, please contact your account executive.

17.5 Recalls

The purchase of this product may be subject to state or local law. If this is not the product you request, please contact your account executive.

17.6 Reinvestigation

The purchase of this product may be subject to state or local law. If this is not the product you request, please contact your account executive.

17.7 Disposal

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17.8 Disposal

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Meloxicam Tablets USP

14 CLINICAL STUDIES
The use of meloxicam for the treatment of the signs and symptoms of pauciarticular or polyarticular juvenile idiopathic arthritis was evaluated in two double-blind, placebo-controlled clinical trials of up to 16 weeks. The use of meloxicam for the treatment of the signs and symptoms of rheumatoid arthritis was evaluated in a series of 12 placebo-controlled, double-blind, parallel-arm, active-controlled trials of up to 16 weeks. The use of meloxicam for the management of signs and symptoms of osteoarthritis was evaluated in six placebo-controlled, double-blind, parallel-arm, active-controlled trials of up to 16 weeks. The use of meloxicam for the treatment of the signs and symptoms of osteoarthritis of the knee and hip was evaluated in a double-blind, placebo-controlled clinical trial of up to 16 weeks. The use of meloxicam for the treatment of the signs and symptoms of fibromyalgia was evaluated in a double-blind, placebo-controlled clinical trial of up to 16 weeks. The use of meloxicam for the treatment of the signs and symptoms of gout was evaluated in a double-blind, placebo-controlled clinical trial of up to 16 weeks. The use of meloxicam for the treatment of the signs and symptoms of osteoarthritis of the hand and shoulder was evaluated in a double-blind, placebo-controlled clinical trial of up to 16 weeks.

15 DRUG INTERACTIONS
Drug Interaction Studies
Following a single dose of meloxicam, the free Cmax plasma concentration was higher in patients with normal renal function as compared to patients with CrCl ≤ 30 mL/min. The free Cmax difference was approximately 25% in patients with mild renal impairment and 40% in patients with moderate renal impairment. In patients with severe renal impairment, the extent of free Cmax plasma concentrations was similar to placebo.

Georg..
What are NSAIDs? 

NSAIDs (nonsteroidal anti-inflammatory drugs) are a class of medicines that are sometimes used to treat the pain and redness, swelling, and heat (inflammation) from medical conditions. NSAIDs include aspirin, ibuprofen, and naproxen sodium. This Medication Guide is about NSAIDs that is written for health professionals. Please address medical inquiries to, (MedicalAffairs@zydususa.com) Tel.: 1-877-993-8779.

Other information about NSAIDs:

Medicines are sometimes taken together. Taking other medicines can change how NSAIDs work or how other medicines work. This may result in side effects. Always talk to a healthcare provider or pharmacist about other medicines you take, including prescription, nonprescription, and herbal medicines.

What are the possible side effects of NSAIDs? 

NSAIDs can cause side effects including:

- Heart attack
- Strokes
- Diabetes
- High blood pressure
- Sunburn risk
- Heartburn
- Nausea
- Vomiting
- Dyspepsia
- Stomach pain, constipation, diarrhea
- Blood in stool
- Gas
- Numbness
- Weakness
- Tiredness
- Feeling light-headed
- Dizziness
- Blurred vision
- Memory problems
- Headache
- Inflammation of the stomach and intestines
- Ulcers
- Bleeding

- More severe side effects of NSAIDs may include:
  - Changes in the color or texture of your skin
  - Loss of appetite
  - Difficulty swallowing
  - Swelling of the face or hands
  - Weight loss
  - Chest pain
  - Swelling of the arms, legs, hands, or feet
  - Numbness or weakness in one part or side of your body
  - Chest pain or heart attack
  - Shortness of breath or trouble breathing

- If you have any of the following symptoms, call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs:

Medicines are sometimes taken together. Taking other medicines can change how NSAIDs work or how other medicines work. This may result in side effects. Always talk to a healthcare provider or pharmacist about other medicines you take, including prescription, nonprescription, and herbal medicines.

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- If you have any of the following symptoms, call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs:

Medicines are sometimes taken together. Taking other medicines can change how NSAIDs work or how other medicines work. This may result in side effects. Always talk to a healthcare provider or pharmacist about other medicines you take, including prescription, nonprescription, and herbal medicines.

What are the possible side effects of NSAIDs? 

NSAIDs can cause side effects including:

- Heart attack
- Strokes
- Diabetes
- High blood pressure
- Sunburn risk
- Heartburn
- Nausea
- Vomiting
- Dyspepsia
- Stomach pain, constipation, diarrhea
- Blood in stool
- Gas
- Numbness
- Weakness
- Tiredness
- Feeling light-headed
- Dizziness
- Blurred vision
- Memory problems
- Headache
- Inflammation of the stomach and intestines
- Ulcers
- Bleeding

- More severe side effects of NSAIDs may include:
  - Changes in the color or texture of your skin
  - Loss of appetite
  - Difficulty swallowing
  - Swelling of the face or hands
  - Weight loss
  - Chest pain
  - Swelling of the arms, legs, hands, or feet
  - Numbness or weakness in one part or side of your body
  - Chest pain or heart attack
  - Shortness of breath or trouble breathing

- If you have any of the following symptoms, call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs:

Medicines are sometimes taken together. Taking other medicines can change how NSAIDs work or how other medicines work. This may result in side effects. Always talk to a healthcare provider or pharmacist about other medicines you take, including prescription, nonprescription, and herbal medicines.