**Meloxicam 7.5 mg and 15 mg tablets**

**What is meloxicam and what is it used for?**

Meloxicam contains the active ingredient meloxicam. Meloxicam belongs to the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines are used to reduce inflammation and pain in joints and muscles.

**Meloxicam is used for:**

* Short-term treatment of a flare-up of osteoarthritis (joint inflammation)
* Long-term treatment of:
* Rheumatoid arthritis
* Ankylosing spondylitis (joint stiffness, also known as Bechterew's disease).

**When Should You Not Use This Medicine Or Take Extra Care**?

When should you not use this medicine?

* You are in the last three months of pregnancy.
* You are a child under the age of 16.
* You are allergic to meloxicam.
* You are allergic to acetylsalicylic acid or non-steroidal anti-inflammatory drugs (NSAIDs).
* You are allergic to any of the substances in this medicine. You can find these substances in section 6.
* You experience any of the following symptoms after taking aspirin or other NSAIDs:
* Wheezing, tightness in the chest, shortness of breath (asthma).
* Nasal congestion due to swelling inside the nose (nasal polyps).
* Skin rash/hives (urticaria).
* Sudden swelling of the skin or mucous membranes, such as swelling around the eyes, face, lips, mouth, or throat that may interfere with breathing (angioedema).
* You have a history of bleeding in your stomach or intestinal tract after previous NSAID treatment.
* You have perforations (holes) in your stomach or intestinal tract.
* You have ulcers or bleeding in your stomach or intestinal tract.
* You have had at least two instances of ulcers or bleeding in the stomach in the past.
* You have severe liver impairment.
* You have severe kidney failure that is not dialyzed.
* You have recently experienced a cerebral hemorrhage (cerebrovascular bleeding).
* You have a bleeding disorder.
* You suffer from severe heart failure.
* Please contact your doctor or pharmacist before using this medicine.

**Do you need to be extra careful with this medicine?**

**Warnings:** Medicines like meloxicam may be associated with a slightly increased risk of a heart attack ("myocardial infarction") or stroke. The risk increases with higher doses and prolonged use of the medicine. Do not exceed the prescribed dose and do not use the medicine longer than prescribed (see section 3).

* If you have heart problems, have had a stroke, or believe you are at risk for these conditions, discuss this with your doctor or pharmacist before taking this medicine. For example, if you have:
* High blood pressure (hypertension)
* High blood glucose levels (diabetes mellitus)
* High blood cholesterol levels (hypercholesterolemia)
* Are a smoker
* If you develop severe allergic reactions, stop using Meloxicam Unichem at the first signs of skin rash, soft tissue damage (damage to mucous membranes), or any other signs of allergy, and contact your doctor.
* Stop treatment immediately if you notice signs of bleeding (e.g., tar-like stools) or an ulcer in your gastrointestinal tract (causing abdominal pain).
* Meloxicam Unichem is not suitable for immediate relief of acute pain.
* Meloxicam Unichem may mask the symptoms of infections (e.g., fever). If you suspect you have an infection, contact your doctor.

**Precautions for use:**

Because the treatment needs to be adjusted before starting to take Meloxicam Unichem, it is important to contact your doctor in the following cases:

* History of esophagitis, gastritis, or another gastrointestinal disease such as Crohn's disease or ulcerative colitis.
* High blood pressure (hypertension)
* Older age
* Heart, liver, or kidney disease
* High blood glucose levels (diabetes mellitus)
* Reduced blood volume (hypovolemia), which may occur due to severe blood loss, burns, surgery, or low fluid intake
* Inability to tolerate certain sugars, as determined by your doctor, as this product contains lactose
* High potassium levels in the blood, as determined by your doctor.

**Contact your doctor or pharmacist before taking this medicine:**

• If you have ever experienced a condition called 'fixed drug eruption' (round or oval red and swollen patches on the skin, usually occurring in the same place(s), blistering, hives, and itching) after using meloxicam or other oxicams (e.g., piroxicam).

Your doctor will monitor your progress during treatment.

**Are you using any other medicines?**In addition to Meloxicam Unichem, are you currently using or have you recently used any other medicines, or is there a possibility that you may use other medicines in the near future? Please inform your doctor or pharmacist.

In particular, inform your doctor or pharmacist before using Meloxicam Unichem if you are using or have used the following medicines:

* Other NSAIDs such as acetylsalicylic acid, ibuprofen, or naproxen.
* Medicines that counteract blood clotting.
* Medicines that dissolve blood clots (thrombolytics).
* Medicines for the treatment of heart and kidney diseases.
* Corticosteroids (used for inflammation or allergic reactions).
* Ciclosporin - used after organ transplants or for severe skin conditions, rheumatoid arthritis, or nephrotic syndrome.
* All diuretic medicines ("water pills"). Your doctor may check your kidney function if you are taking diuretics.
* Medicines for the treatment of high blood pressure (e.g., beta-blockers).
* Lithium - used for the treatment of mood disorders.
* Selective serotonin reuptake inhibitors (SSRIs) - used for the treatment of depression.
* Methotrexate - used for the treatment of tumors or severe uncontrolled skin conditions and active rheumatoid arthritis.
* Colestyramine - used to lower cholesterol levels.
* If you are a woman using an intrauterine contraceptive device (IUD), also known as an "IUD."

If you are unsure, please contact your doctor or pharmacist.

**Meloxicam Unichem with food and drink:** The tablets should be taken with a glass of water or another liquid and with food.

**Pregnancy, breastfeeding, and fertility:**

**Pregnancy:** Do not use this medicine in the last three months of pregnancy; it may harm your unborn child or cause problems during delivery. Your unborn child may experience kidney and heart problems. The medicine can affect your and your baby's susceptibility to bleeding and may result in a later or longer-than-expected delivery. Do not use this medicine during the first six months of pregnancy unless absolutely necessary and recommended by your doctor. If you need treatment during this period or while trying to conceive, the lowest possible dose should be used, and the treatment should be kept as short as possible. From week 20 of pregnancy, if used for more than a few days, this medicine may cause kidney problems in your unborn child, which can lead to too little amniotic fluid around the baby (oligohydramnios) or constriction of a blood vessel in your baby's heart (ductus arteriosus). If you need treatment for longer than a few days, your doctor may recommend additional checks.

**Breastfeeding:** This product is not recommended during breastfeeding. Ask your doctor or pharmacist for advice before taking this medicine.

**Fertility:** Meloxicam Unichem may make it difficult to conceive. Inform your doctor if you plan to become pregnant or if you have difficulty getting pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:** Visual disturbances, including blurred vision, dizziness, drowsiness, vertigo, or other central nervous system disorders, may occur with this product. If you experience these symptoms, do not drive vehicles or operate machinery.

**Meloxicam Unichem tablets contain lactose and sodium citrate:** If your doctor has told you that you have an intolerance to certain sugars, please contact your doctor before taking this medicine.

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, meaning it is essentially 'sodium-free.'

**How to use this medicine:** Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage is as follows:

**Flare-up of osteoarthritis:** 7.5 mg (one 7.5 mg tablet or half a 15 mg tablet) per day. This can be increased to 15 mg per day.

**Rheumatoid arthritis:** 15 mg per day (two 7.5 mg tablets or one 15 mg tablet). This can be reduced to one 7.5 mg tablet or half a 15 mg tablet per day.

**Ankylosing spondylitis:** 15 mg (two 7.5 mg tablets or one 15 mg tablet) per day. This can be reduced to one 7.5 mg tablet or half a 15 mg tablet per day.

The tablets should be taken with water or another liquid during a meal.

The maximum recommended dosage of 15 mg per day should not be exceeded.

If any of the conditions mentioned under the heading "When should you be extra careful with this medicine?" apply to you, your doctor may decide to lower your dosage to 7.5 mg per day.

Meloxicam Unichem should not be given to children and young adults under the age of 16 years.

Consult your doctor or pharmacist if you do not notice an improvement in your condition or if you think the effect of Meloxicam Unichem is too strong or too weak.

**Have you taken too much of this medicine?**

* If you have taken too many tablets or suspect an overdose, contact your doctor immediately or go to the nearest hospital.
* The symptoms of acute overdose with NSAIDs are usually limited to:
* Lack of energy (lethargy)
* Drowsiness
* Nausea and vomiting
* Pain in the abdominal area (epigastric pain)
* These symptoms generally improve when you stop taking Meloxicam Unichem. You may experience gastrointestinal bleeding.
* Severe poisoning can lead to serious side effects (see section 4)
* High blood pressure (hypertension)
* Acute kidney failure
* Liver failure (hepatic dysfunction)
* Decreased/flat or stopped breathing (respiratory depression)
* Loss of consciousness (coma)
* Seizures (convulsions)
* Sudden severe drop in blood pressure leading to loss of consciousness (cardiovascular collapse)
* Cardiac arrest
* Immediate allergic (hypersensitivity) reaction, including:
* Fainting
* Shortness of breath
* Skin reactions

**Did you forget to take this medicine?**Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

**If you stop using this medicine**Contact your doctor before stopping the use of Meloxicam Unichem. Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

**Possible side effects**Like all medicines, this medicine can have side effects, although not everyone gets them.

Stop using Meloxicam Unichem and consult a doctor or the nearest hospital immediately if you experience any of the following side effects:

**Allergic (hypersensitivity) reactions; these can occur in the form of:**

* Skin reactions, such as itching (pruritus), blistering or peeling of the skin, which can be severe (Stevens-Johnson syndrome and toxic epidermal necrolysis), soft tissue damage (mucous membrane damage), or erythema multiforme. Erythema multiforme is a severe allergic skin reaction that can cause spots, red edges, or purple or blistered areas. It can also affect the mouth, eyes, and other moist body surfaces.
* Swelling of the skin or mucous membranes, such as swelling around the eyes, face, and lips, mouth, or throat, which may make breathing difficult, swollen ankles or legs (edema of the lower limbs)
* Shortness of breath or asthma attack
* Inflammation of the liver (hepatitis). This can cause symptoms such as:
* Yellowing of the skin or eyeballs (jaundice)
* Abdominal pain
* Loss of appetite

**Any gastrointestinal side effect, in particular:**

* Bleeding (causing tarry stools)
* Ulcers in your gastrointestinal tract (causing abdominal pain)

Bleeding from the gastrointestinal tract (gastrointestinal bleeding), formation of ulcers or perforations in the gastrointestinal tract can sometimes be severe and potentially fatal, especially in elderly patients.

If you have previously experienced gastrointestinal symptoms due to long-term use of NSAIDs, seek immediate medical advice, especially if you are elderly. Your doctor will monitor your progress during treatment.

If you experience blurred vision, do not drive vehicles or operate machinery.

**Common side effects of non-steroidal anti-inflammatory drugs (NSAIDs)**The use of some non-steroidal anti-inflammatory drugs (NSAIDs) may be associated with a slight increase in the risk of arterial thrombotic events, possibly leading to a heart attack (myocardial infarction) or stroke (apoplexy), especially at high doses and with long-term treatment.
Fluid retention (edema), high blood pressure (hypertension), and heart failure have been reported with NSAID treatment.

The most commonly observed side effects affecting the gastrointestinal system (gastrointestinal cases) are:

* Ulcers of the stomach and duodenum (peptic/gastroduodenal ulcers)
* A hole in the wall of the intestines (perforation) or bleeding from the gastrointestinal tract (sometimes fatal, especially in elderly patients).
* The following side effects have been reported after NSAID administration:
* Nausea and vomiting
* Watery stools (diarrhea)
* Flatulence (flatulence)
* Constipation (obstipation)
* Heartburn/bloating (dyspepsia)
* Abdominal pain
* Tarry stools due to bleeding in the gastrointestinal tract (melena)
* Vomiting of blood (hematemesis)
* Inflammation resulting in the development of mouth ulcers (ulcerative stomatitis)
* Exacerbation of inflammation of the gastrointestinal tract (exacerbation of colitis or Crohn's disease).
* Gastritis has been observed less frequently.
* Side effect of meloxicam - the active ingredient in Meloxicam Unichem

**Very common: occurs in more than 1 in 10 users**

* Heartburn/bloating (dyspepsia)
* Nausea and vomiting
* Abdominal pain
* Constipation (obstipation)
* Flatulence (flatulence)
* Watery stools (diarrhea).

**Common: occurs in more than 1 in 10 users:** Headache

**Sometimes: occurs in 1 to 10 in 1,000 users:** Dizziness

* A feeling of dizziness or vertigo
* Drowsiness
* Anemia
* High blood pressure (hypertension)
* Flushing (temporary redness of the face and neck)
* Sodium and water retention (retention of salt and fluid in the body)
* Elevated potassium levels (hyperkalemia). This can lead to symptoms such as:
* Changes in your heart rhythm (arrhythmia)
* Palpitations (when you feel your heartbeat more than usual)
* Muscle weakness
* Burping
* Gastritis (stomach inflammation)
* Gastrointestinal bleeding
* Mouth inflammation (stomatitis)
* Immediate allergic (hypersensitivity) reactions
* Itching (pruritus)
* Skin rash
* Swelling caused by fluid retention (edema), including swollen ankles/legs (lower limb edema)
* Sudden swelling of the skin or mucous membranes, such as swelling around the eyes, face, lips, mouth, or throat, which may interfere with breathing (angioedema)
* Temporary abnormalities in liver function values (e.g., elevated liver enzymes like transaminases or an increase in the bile pigment bilirubin). Your doctor can detect this with a blood test
* Abnormalities in laboratory tests of kidney (renal) function (e.g., increased creatinine or urea)

**Rare: occurs in 1 to 10 out of 10,000 users**

* Mood disorders
* Nightmares
* Abnormal blood test results: these side effects may lead to an increased risk of infection and symptoms such as bruising and nosebleeds
* Ringing in the ears (tinnitus)
* Feeling your heartbeat (palpitations)
* Ulcers of the stomach and duodenum (peptic/gastroduodenal ulcers)
* Inflammation of the esophagus (esophagitis)
* Onset of asthma attacks (observed in people allergic to aspirin or other NSAIDs)
* Severe blistering of the skin or peeling (Stevens-Johnson syndrome and toxic epidermal necrolysis)
* Hives (urticaria)
* Vision disturbances including:
* Blurred vision
* Inflammation of the eyeballs or eyelids (conjunctivitis)
* Colitis (inflammation of the colon)

**Very rarely: occurs in less than 1 in 10,000 users**

* Blistering skin reactions and erythema multiforme
* Erythema multiforme is a severe allergic skin reaction that can cause spots, red edges, or purple or blistering spots. It can also affect the mouth, eyes, and other moist body surfaces.
* Hepatitis (liver inflammation). This can cause symptoms such as:
* Yellowing of the skin or eyeballs (jaundice)
* Abdominal pain
* Loss of appetite
* Acute kidney failure (renal failure), especially in patients with risk factors such as heart disease, diabetes, or kidney disease
* A hole in the intestinal wall (perforation)

**How to store this medicine?**

* Keep this medicine out of the sight and reach of children.
* Do not use this medicine after the expiry date which is stated on the blister or carton after EXP. The last day of that month is the expiry date.
* There are no special storage conditions for Meloxicam Unichem.
* Do not dispose of medications in wastewater or household waste. Ask your pharmacist how to dispose of medications you no longer use. These measures will help protect the environment.