PACKAGE LEAFLET: INFORMATION FOR THE USER

Meloxicam 7.5 mg and 15 mg Tablets

Meloxicam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Meloxicam Tablets are and what they are used for
2. What you need to know before you take Meloxicam Tablets
3. How to take Meloxicam Tablets
4. Possible side effects
5. How to store Meloxicam Tablets
6. Contents of the pack and other information

1.What Meloxicam Tablets are and what they are used for

Meloxicam belongs to a group of medicines called **non-steroidal anti-inflammatory drugs (NSAIDs)** which are used to reduce inflammation and pain in joints and muscles. Meloxicam Tablets are used for the:

- short-term treatment of flare ups of osteoarthritis
- long-term treatment of
  - rheumatoid arthritis
  - ankylosing spondylitis (also known as Bechterew's Disease)

2.What you need to know before you take Meloxicam Tablets

Do not take Meloxicam Tablets in the following circumstances:

- during the last three months of pregnancy
- children and adolescents under 16 years of age
- allergy to meloxicam
- allergy (hypersensitivity) to aspirin or other anti-inflammatory medicines (NSAIDs)
- allergy (hypesensitivity) to any of the other ingredients of this medicine (listed in section 6)
- any of the following signs after taking aspirin or other NSAIDs:
  - wheezing, chest tightness, breathlessness (asthma)
  - nasal blockage due to swellings in the lining in your nose (nasal polyps)
  - skin rashes/nettle rash (urticaria)
  - sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioneurotic oedema)
- after previous therapy with NSAIDs and history of
  - bleeding in your stomach or intestines
  - holes (perforations) in your stomach or intestines
- ulcers or a bleeding in your stomach or intestines
- recent or history of stomach or peptic ulcers or bleeding (ulceration or bleeding occurring at least twice)
- severely impaired liver function
- non-dialysed kidney failure
- recent bleeding in the brain (cerebrovascular bleeding)
- any kind of bleeding disorders
- severe heart failure
- intolerance to some sugars as this product contains lactose (See also "Meloxicam Tablets contain lactose")

Tell your doctor if you are not sure about any of the conditions stated above.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Meloxicam Tablets.

Warnings

Medicines such as meloxicam may be associated with a small, increased risk of heart attack (myocardial infarction) or stroke (apoplexy). Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose. Do not take Meloxicam Tablets for longer than they are prescribed for you (see section 3 "How to take Meloxicam Tablets").

If you have heart problems, previous stroke or think that you might be at risk of these, you should discuss your treatment with your doctor or pharmacist. For example if you:

- have high blood pressure (hypertension)
- have high levels of sugar in the blood (diabetes mellitus)
- have high levels of cholesterol in the blood (hypercholesterolemia)
- are a smoker

Stop your treatment with Meloxicam Tablets immediately as soon as you notice bleeding (causing tar-coloured stools) or ulceration of your digestive tract (causing abdominal pain).

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of meloxicam, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
If you have developed Stevens-Johnston syndrome or toxic epidermal necrolysis with the use of meloxicam, you must not be re-started on meloxicam at any time. If you develop a rash or these skin symptoms, stop taking meloxicam, seek urgent advice from a doctor and tell them that you are taking this medicine.

Meloxicam Tablets are not appropriate if you require immediate relief from acute pain.

Meloxicam Tablets may hide the symptoms of infection (e.g. fever). If you think you may have an infection you should see your doctor.

Precautions for use

As it will be necessary to adjust the treatment, it is important to ask your doctor's advice before you take Meloxicam Tablets in case of:

- history of inflammation of the gullet (oesophagitis), inflammation of the stomach (gastritis) or a history of any other disease of the digestive tract (e.g. Crohn's Disease or Ulcerative Colitis)
- high blood pressure (hypertension)
- older age
- heart, liver or kidney disease
- high levels of sugar in the blood (diabetes mellitus)
- reduced blood volume (hypovolaemia) which may occur if you have a serious blood loss or burn, surgery or low fluid intake
- intolerance to some sugars diagnosed by your doctor as this product contains lactose
- high potassium levels in the blood previously diagnosed by your doctor

Talk to your doctor or pharmacist before taking Meloxicam Tablets if you have ever developed fixed drug eruption (round or oval patches of redness and swelling of the skin that usually recurs at the same site(s), blistering, hives and itching) after taking meloxicam or other oxicams (e.g. piroxicam).

Your doctor will need to monitor your progress whilst on treatment.

Other medicines and Meloxicam Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

In particular tell your doctor or pharmacist if you are taking/have taken any of the following:

- other NSAIDs, e.g. aspirin, ibuprofen or naproxen
- medicines which prevent blood clotting, such as warfarin or heparin
- medicines which break down blood clots (thrombolytics)
- medicines to treat heart and kidney diseases
- corticosteroids (e.g. used against inflammation or allergic reactions)
- cyclosporine – used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome
- any diuretic medicine ("water tablets"). Your doctor may need to monitor your kidney function if you are taking diuretics
- medicines used to treat high blood pressure (e.g. Beta-blockers)
- lithium used to treat mood disorders
- selective Serotonin re-uptake inhibitors (SSRIs) used in the treatment of depression
- methotrexate – used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis
- cholestyramine - used to lower cholesterol levels

If you are in doubt about any of these medicines, ask your doctor or pharmacist.

Meloxicam Tablets with food and drink

The tablets should be taken with a drink of water or other liquid and with food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take meloxicam tablets if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take meloxicam tablets during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, meloxicam tablets can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

Meloxicam is not recommended during breast-feeding.

Fertility

Meloxicam Tablets may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Visual disturbances, including blurred vision, dizziness, drowsiness, vertigo or other central nervous system disturbances may occur with this product. If affected do not drive or operate machinery.

Meloxicam Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Information on sodium content

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium free'.

3.How to Take Meloxicam Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Flare-ups of osteoarthritis:

7.5 mg once a day. This may be increased to 15 mg once a day.

Rheumatoid arthritis and ankylosing spondylitis:
15 mg once a day. Your doctor may reduce your dose to 7.5 mg a day.

Meloxicam Tablets are for oral use. They should be taken with a drink of water or other liquid and with food.

The 15 mg tablets can be divided into two equal halves, allowing a 7.5 mg dose to be achieved by taking half a tablet.

Do not exceed the recommended maximum dose of 15 mg a day.

If any of the statements under the heading "Warnings and Precautions" apply to you, your doctor may restrict your dose to 7.5 mg once a day.

Use in children and adolescents:

Meloxicam Tablets should NOT be given to children and adolescents under 16 years of age.

If you feel the effect of Meloxicam Tablets is too strong or too weak or if after several days you do not feel an improvement in your condition, talk to your doctor or pharmacist.

If you take more Meloxicam Tablets than you should:

Whether you have taken too many tablets or suspect an overdose, contact your doctor immediately or go to your nearest hospital immediately.

Symptoms following acute NSAID overdose are usually limited to:

- lack of energy (lethargy)
- drowsiness
- feeling sick (nausea) and being sick (vomiting)
- pain in the area of the stomach (epigastric pain)

These symptoms generally get better when you stop taking Meloxicam Tablets. You may suffer from bleeding of the stomach or intestines (gastrointestinal bleeding).

Severe poisoning may result in serious drug reaction (see section 4)

- high blood pressure (hypertension)
- acute kidney (renal) failure
- liver (hepatic) dysfunction
- reduction/flattening or standstill of breathing (respiratory depression)
- loss of consciousness (coma)
- seizures (convulsions)
- collapse of the blood circulation (cardiovascular collapse)
- standstill of the heart (cardiac arrest)
- immediate allergic (hypersensitivity) reactions, including
  - fainting
  - shortness of breath
  - skin reactions

If you forget to take Meloxicam Tablets:

If you forget to take your tablets, take your recommended dose as soon as you remember, unless it is nearly time for your next dose. Do NOT take a double dose to make up for a forgotten dose.

If you stop taking Meloxicam Tablets:

Do not stop taking the tablets without first checking with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Meloxicam Tablets and consult a doctor or your nearest hospital if you notice:

Any allergic (hypersensitivity) reactions, which may appear in the form of:

- skin reaction, such as itching (pruritis), blistering or peeling of the skin, which can be potentially life threatening skin rashes (Stevens-Johnston syndrome, toxic epidermal necrolysis), lesions of soft tissues (mucosal lesions) or erythema multiforme (see section 2). Erythema multiforme is a serious allergic skin reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces.
- swelling of skin or mucosa, such as swelling around the eyes, face and lips, mouth or throat, possibly making breathing difficult, swollen ankles or legs (oedema 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 the eyeballs (jaundice)
  - pain in the abdomen
  - loss of appetite

Any side effect of the digestive tract, especially:

- bleeding (causing tar-coloured stools)
- ulceration of your digestive tract (causing abdominal pain)

Bleeding of the digestive tract (gastrointestinal bleeding), formation of ulcers or formation of a hole in the digestive tract (perforation) may sometimes be severe and potentially fatal, especially in the elderly.

If you have previously suffered from any symptoms of the digestive tract due to long term use of NSAIDs, seek medical advice immediately, especially if you are elderly. Your doctor may monitor your progress whilst on treatment.

If affected by visual disturbances do not drive or operate machinery.

General side effects of non-steroidal anti-inflammatory medicines (NSAIDs)

The use of some non-steroidal anti-inflammatory drugs (NSAIDs) may be associated with a small increased risk of occlusion of arterial vessels (arterial thrombotic events), e.g. heart attack (myocardial infarction) or stroke (apoplexy), particularly at high doses and in long term treatment.

Fluid retention (oedema), high blood pressure (hypertension) and heart failure (cardiac arrest) have been reported in association with NSAID treatment.

The most commonly observed side effects affect the digestive tract (gastrointestinal events):

- ulcers of the stomach and upper part of the small bowels (peptic/gastroduodenal ulcers)
- a hole in the wall of the bowels (perforation) or bleeding of the digestive tract (sometimes fatal, particularly in the elderly)

The following side effects have been reported after NSAID administration:

- feeling sick (nausea) and being sick (vomiting)
- loose stools (diarrhoea)
- flatulence
- constipation
- indigestion (dyspepsia)
- abdominal pain
- tar-coloured stools due to bleeding in the digestive tract (melaena)
- vomiting of blood (haematemesis)
- inflammation with building of ulcers in the mouth (ulcerative stomatitis)
- worsening of inflammation of the digestive tract (e.g. exacerbation of colitis or Crohn's disease)

Less frequently, inflammation of the stomach (gastritis) has been observed.

Side effects of meloxicam – the active ingredient of Meloxicam Tablets

Very common: may affect more than 1 in 10 people

- gastrointestinal adverse events such as indigestion (dyspepsia), feeling sick (nausea) and being sick (vomiting), abdominal pain, constipation, flatulence, loose stools (diarrhoea)

Common: may affect up to 1 in 10 people

- headache

Uncommon: may affect up to 1 in 100 people

- dizziness (light-headedness)
- a feeling of dizziness or spinning (vertigo)
- somnolence (drowsiness)
- anaemia (reduction of the concentration of the red blood pigment haemoglobin)
- increase in blood pressure (hypertension)
- flushing (temporary redness of the face and neck)
- sodium and water retention
- increased potassium levels (hyperkalaemia). This can lead to symptoms such as
  - changes to your heartbeat (arrhythmias)
  - palpitations (when your heart beats more than usual)
  - muscle weakness
- eructation
- inflammation of the stomach (gastritis)
- bleeding of the digestive tract
- inflammation of the mouth (stomatitis)
- immediate allergic (hypersensitivity) reactions
- itching (pruritis)
- skin rash
- swelling caused by fluid retention (oedema), including swollen ankles/legs (oedema of the lower limbs)
- sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioneurotic oedema)
- momentary disturbance of liver function tests (e.g. raised liver enzymes like transaminases or an increase of the bile pigment bilirubin). Your doctor can detect these using a blood test.
- disturbance of laboratory tests investigating kidney (renal) function (e.g. raised creatinine or urea)

Rare: may affect up to 1 in 1000 people

- mood disorders
- nightmares
- abnormal blood count, including
  - abnormal differential blood count
  - decreased number of white blood cells (leucocytopenia)
  - decreased number of blood platelets (thrombocytopenia)

  These side effects may lead to increased risk of infection and symptoms such as bruising and nosebleeds.
- ringing in the ear (tinnitus)
- feeling your heartbeat (palpitations)
- ulcers of the stomach or upper part of the small bowel (peptic/gastroduodenal ulcers)
- inflammation of the gullet (oesophagitis)
- onset of asthma attacks (seen in people who are allergic to aspirin or other NSAIDs)
- severe blistering of the skin or peeling (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- nettle rash (urticaria)
- visual disturbances
  - blurred vision
  - conjunctivitis (inflammation of the eyeball or eyelids)
- inflammation of the large bowel (colitis)

Very rare: may affect up to 1 in 10,000 people

- blistering reactions of the skin (bullous reactions) and erythema multiforme. Erythema multiforme is a serious allergic reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces
- inflammation of the liver (hepatitis). This can cause symptoms such as:
  - yellowing of the skin or the eyeballs (jaundice)
  - pain of the abdomen
  - loss of appetite
- acute failure of the kidneys (renal failure) in particular in patients with risk factors such as heart disease, diabetes or kidney disease
- a hole in the wall of the bowels (perforation)

Not known: frequency cannot be estimated from the available data

- confusion
- disorientation
- shortness of breath and skin reactions (anaphylactic/anaphylactoid reactions)
- rashes caused by exposure to sunlight (photosensitivity reactions)
- heart failure (cardiac failure) has been reported in association with NSAID treatment
- Complete loss of specific types of white blood cells (angranulocytosis), especially in patients who take Meloxicam Tablets together with other drugs that are potentially inhibitory, depressant or destructive to a component of bone marrow (myelotoxic drugs). This can cause:
  - sudden fever
  - sore throat
  - infections
- pancreatitis (inflammation of the pancreas)
- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching.

Side effects caused by non-steroidal anti-inflammatory medicines (NSAIDs), but not yet seen after taking Meloxicam Tablets

Changes to the kidney structure resulting in acute kidney failure:

- very rare cases of kidney inflammation (interstitial nephritis)
- death of some of the cells within the kidney (acute tubular or papillary necrosis)
- protein in the urine (nephrotic syndrome with proteinuria)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5.How to store Meloxicam Tablets

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 carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Meloxicam Tablets do not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6.Contents of the pack and other information

What Meloxicam Tablets contain

- The active substance is Meloxicam. Each tablet contains 7.5 mg or 15 mg of meloxicam.
- The other ingredients are sodium citrate, lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate.

What Meloxicam Tablets look like and contents of the pack

Meloxicam 7.5 mg Tablets are light yellow, round, biconvex bevelled edge tablets with B and 18 on one side and plain on the other side.
Meloxicam 15 mg Tablets are light yellow, round, biconvex bevelled edge tablets with B and 19 on either side of a scoreline on one side and plain on the other side.
Meloxicam 7.5 mg and 15 mg Tablets are available in blister packs containing 30 tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Niche Generics Ltd., 1 The Cam Centre, Wilbury Way, Hitchin, Hertfordshire,
SG4 0TW, United Kingdom

Manufacturer:
Niche Generics Ltd., Unit 1,
Waterloo Farm Courtyard,
Stotfold Road,
Arlesey, SG15 6XP,
United Kingdom

This leaflet was last revised in: June 2023

Niche Generics Limited,
Unit 5, 151 Baldoyle Industrial Estate, Baldoyle,
Dublin 13, Ireland
Tel: +353 (0)18167300
e-mail: artwork@nichegenerics.ie

Title:	Meloxicam 7.5mg/15mg Niche UK
MA Number/s:	PL 19611/0078 and 19611/0079
Date of Origination:	04/05/2005
Dimensions:	580mm x 160mm
Colours:	Black ■
Item Code:	N/A
Pharmacode:	TBD
Version Number:	27
Revision Date:	20/06/2023
Reason for Revision:	Updates to sections 2 and 4 to implement the outcome of a PSUR procedure (PSUSA/00010474/202207) - include information about 'fixed drug eruption'.

Software: QuarkXpress 4.1