Product Name : **Meloxicam 7.5/15 mg Tablets**

Insert Size : **210 (L) x 310 (H)mm (Back Side)**

Carton : K Line Development Date : **08.06.2022**

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PHARMA CODE

Package leaflet: Information for the patient

Meloxicam 7.5 mg Tablets
Meloxicam 15 mg Tablets

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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What is Meloxicamis and what it is used for?

Meloxicam belongs to a group of drugs called Non-Steroidal Anti-InflammatoryDrugs (NSAIDs), which are used to reduce inflammation and pain in the joints and muscles.

Meloxicam Tablets are used for the:
- short-term treatment of flare ups of osteoarthrosis
- long-term treatment of
  – rheumatoid arthritis
  – ankylosing spondylitis (also known as Bechterew's Disease)

2. What you need to know before you take Meloxicam

Do not takeMeloxicam :
- if you are allergic to meloxicam or any of the other ingredients of this medicine(listed in section 6)
- if you are allergic to aspirin or other anti-inflammatory medicines or other NSAIDs
- during the last three months of pregnancy
- if you are under 16 years of age
- if you have severly impaired liver function
- if you have ulcers of bleeding in your stomach or intestines
- if you have non-dialysed severe kidney failure
- if you have had any of the following signs after taking aspirin or other NSAIDs
– wheezing, chest tightness, breathlessness (asthma)
– nasal blockage due to swelling in the lining of you nose (nasal polyps)
– sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possible making breathing difficult (angioneurotic oedema)
- if after previous therapy with NSAIDs you have a history of;
– bleeding in your stomach or intestines
– holes (perforations) in your stomach or intestines
- if you have recent or a history of ulcers of bleeding in your stomach or intestines (ulceration or bleeding occuring at least twice)
- if you have had recent bleeding in the brain (cerebrovascular bleeding)
- if you have severe heart failure

Warnings and precautions

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

If you have heart problems, previous stroke or think that you might be at risk of these conditions, 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

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

NSAIDs including meloxicam may mask the symptoms (e.g. fever) of an underlying infection. If you develop signs of infection, or if the symptoms worsen, you should contact your doctor.

If you are a woman, meloxicam may make it more difficult to conceive. Tell your doctor if you are planning to become pregnant or are having problems conceiving.

You should not take meloxicam if you are undergoing fertility treatment.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermalnecrolysis) 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 rashesare 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 month of treatment. If you have developed Stevens-Johnson 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 him that you are taking this medicine**

Your doctor may want to monitor your liver and kidneys during your treatment with meloxicam, in order to make sure they are working properly.

As it will be necessary to adjust the treatment, it is important to ask for your doctor's advice before you take meloxicam in the following cases:
- history of inflammation of the gullet (oesophagitis), inflammation of the stomach (gastritis) or any other disease of the digestive tract e.g. ulcerative colitis or Crohn's disease
- high blood pressure
- older age
- heart, liver or kidney disease
- high levels of sugar in the blood (diabetes mellitus)
- reduce blood volume (hypervolemia) which may occur if you have a serious blood loss or burn, sugary or low fluid intake
- high potassium levels in the blood previously diagnosed by your doctor

Your doctor may monitor your progress whilst on treatment.

Higher doses than recommended can entail serious risks. Therefore, do not exceed the recommended daily dose, and do not use other anti-inflammatory medicines(NSAIDs) at the same time. This is especially important if you are elderly, as the risk of side effects is higher.

Other medicines and Meloxicam

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 or have taken any of the following:
- other NSAIDs
- medicines which prevent the blood clotting
- medicines which break down blood clots (thrombolytics)
- medicines to treat heart and kidney disease
- corticosteroids
- ciclosporin - used after organ transplants, or for severe skin conditions,
- rheumatoid arthritis or nephrotic syndrome
- any diuretic medicine ("water tablets"). Your doctor may want to monitor your
- kidney function if you are taking diuretics
- lithium - used to treat mood disorders
- selective serotonin re-uptake inhibitors – used in the treatment of depression
- methotrexate - used to treat tumours or severe uncontrolled skin conditions and
- active rheumatoid arthritis
- cholestyramine - mainly used to lower cholesterol levels
- if you are a woman who uses an intrauterine contraceptive device (IUD), usually known as a coil.

Taking other anti-inflammatory medicines or medicines which prevent or break down blood clots at the same time as meloxicam may increase the risk of stomach or intestinal ulcers, bleeding and damage to the gut and stomach lining. The use of these medicines at the same time as meloxicam is therefore not recommended.

Pregnancy and 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.

During the first 6 months of pregnancy your doctor may prescribe this medicine if necessary.

During the last 3 months of pregnancy, do not use this product because meloxicam can have serious side effects for your baby, in particular heart, lungs and kidney problems even with only one administration.

This medicine should not be used if you are breast-feeding.

This medicine is not recommended in women attempting to have a baby. The use of meloxicam may impair female fertility. In women who have difficulties in becoming pregnant or who are undergoing investigations of infertility, withdrawal of meloxicam should be considered.

Driving and using machines

Meloxicam may affect your ability to drive or use machines, due to possibility of dizziness, drowsiness and blurred vision as side effects. If you experience these effects, do not drive or operate machinery until the symptoms wear off. Ask your doctor or pharmacist for advice.

Meloxicam contains lactose monohydrate and sodium

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

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

3. How to take Meloxicam

Always take this medicine exactly as your doctor or pharmacist has told you. Checkwith your doctor or pharmacist if you are not sure.

Tablets should be swallowed with a glass of water during a meal.

The recommended dose is as follows.

Flare-ups of osteoarthrosis

One 7.5mg tablet a day, which may be increased after consultation with your doctorto 15mg a day (two 7.5mg tablets or one 15mg tablet).

Rheumatoid arthritis

One 15mg tablet per day (or two 7.5mg tablets). This may be reduced to one 7.5mg tablet once a day.

Ankylosing spondylitis

One 15mg tablet per day (or two 7.5mg tablets). This may be reduced to one 7.5mg tablet once a day.

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

Elderly patients and patients with impaired kidney or liver function

For elderly patients, the recommended dose for long-term treatment of rheumatoid arthritis or ankylosing spondylitis is 7.5mg per day.

Also, patients at high risk of side effects should start treatment with 7.5mg a day.

If you have severe kidney disease and receive dialysis, the maximum dose of meloxicam should be 7.5mg per day.

Use in children and adolescents

Meloxicam must not be given to children and adolescents under 16 years of age.

Contact your doctor or pharmacist if you are not sure how to take this medicine or if you feel that the effect of meloxicam is too strong or too weak.

If you take more Meloxicam than you should

Go to your nearest hospital emergency department or contact your doctor immediately. Take the empty container and any remaining medicine with you.

Symptoms of overdose are usually limited to lethargy, drowsiness, nausea, vomiting and pain in the stomach. These symptoms are generally reversible. You may suffer

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from bleeding of the stomach or intestines (gastrointestinal bleeding). Severe overdose, however, may result in serious adverse drug reactions (see section 4,"Possible Side Effects").

If you forget to take Meloxicam

If you miss a dose, do not worry. If you remember within a few hours of the missed dose take it as soon as possible, but if it is almost time for your next dose then skip the forgotten one and continue as before. Do not take a double dose to make up fora forgotten dose.

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 and contact your doctor or nearest hospital immediately if you notice:

Any allergic reaction which may appear in the form of

- skin reactions, such as itching (pruritis) blistering or peeling of the skin which can be severe (Steven-Johnson Syndrome and Toxic epidermal necrosis) lesions of the soft tissue (mucosal lesions) or erythema multiforme. Erythema multiforme is a serious allergic reaction causing spots, red welts or purple or blistered area. It can 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, possible 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 whites of the eyes
- pain in the abdomen
- loss of appetite

Any side effect of the digestive tract especially

- bleeding (causing tar coloured stools) or vomiting of blood (haematemesis)
- ulceration of the 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) mays 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

Side effects which may occur with Meloxicam tablets are:

Very Common (may affect more than 1 in 10 people)

- indigestion (dyspepsia)
- feeling sick (nausea) or being sick (vomiting)
- stomach ache (abdominal pain)
- constipation
- passing wind (flatulence)
- loose stool (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 (which may make you feel tired and lacking in energy)
- increase in blood pressure
- flushing (temporary redness to face and neck)
- sodium and water retention
- increase potassium level (hyperkalaemia). this can lead to symptoms such as
  – changes in the heartbeat (arrythmias) when you feel your heart is skipping beats or beating too fast
  – palpitations (when you feel your heart is beating more than usual)
  – muscle weakness
- eructation (belching)
- inflammation of the stomach (gastritis)
- inflammation of the mouth (stomatitis)
- immediate allergic reactions (hypersensitivity)
- itching (pruritis)
- skin rash
- swelling caused by fluid retention (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 1,000 people)

- changes in mood
- nightmares
- abnormal blood count including decrease in the white blood cells platelets.
  This may lead to increased risk of infections and symptoms such as increased bruising or nosebleeds
- ringing in the ears (tinnitus)
- feeling your heartbeat (palpitations)
- ulcers of the stomach or small intestines (peptic/gastroduodenal ulcers)
- inflammation of the gullet (oesophagitis)
- nettle rash (urticaria)
- visual disturbances including blurred vision
- inflammation of the eyeball or eyelids (conjunctivitis)
- inflammation of the large bowel (colitis)

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

- acute failure of the kidneys (renal failure) in particular in patients with risk factors such as heart disease, diabetes or kidney disease
- complete loss of specific types of white blood cells (agranulocytosis), especially in patients who take meloxicam together with other drugs that are potentially inhibitory, depressant or destructive to a component of the bone marrow (myelotoxic drugs). This can cause:
  – sudden fever
  – sore throats
  – infections

Not known (frequency cannot be estimated from the available data)

- confusion
- disorientation
- heart failure (cardiac failure) has been reported in association with NSAID treatment
- inflammation of the pancreas (pancreatitis)
- sensitivity to sunlight (photosensitivity)

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

- 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 at: www.mhra.gov.uk/yellowcardor 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 out of the sight and reach of children.

Do not store above 25° C.

Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What Meloxicam contains

The active substance is meloxicam.Each Tablets contains 7.5mg or 15 mg meloxicam.

Other ingredients are:Maize starch, pregelatinised maize starch, colloidal silicon dioxide, trisodium citrate, lactose monohydrate, microcrystalline cellulose and magnesium stearate.

What Meloxicam look like and contents of the pack

Meloxicam 7.5 mg Tablets are yellow coloured, 7.0mm, circular, flat, beveled uncoated tablet with central breakline on one side and plain on the other side.

Meloxicam 15 mg Tablets are yellow coloured, 10.00mm, circular, flat, beveled uncoated tablet with central breakline on one side and plain on the other side.

The score line is only to help break the tablet for ease of swallowing and not to divide into equal doses.

Meloxicam Tablets are packed in blister packsof 10, 30 and 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

Cygnus Pharma Limited

72 Cardigan Street,
Luton
LU1 1RR
UK

Manufacturer:

Ascenders Consulting Services Limited

110 Butterfield, Great Marlings,
Luton, LU2 8DL,
United Kingdom

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