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Meloxicam 7.5 mg and 15 mg Tablets

Package leaflet information for the patient

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

What is in this leaflet:

1. What Meloxicam Tablets is and what it is 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 is and what it is used for

The name of your medicine is Meloxicam Tablets 7.5 mg and 15 mg Tablets (referred to as Meloxicam Tablets in this leaflet).
Meloxicam Tablets belongs to a group of drugs called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which are used to reduce inflammation and pain in the joints and muscles.

Meloxicam Tablets are used for
- 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 Tablets

Do not take Meloxicam Tablets:
- if you are allergic to Meloxicam Tablets 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 severely impaired liver function
- if you have ulcers or 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 your 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 or bleeding in your stomach or intestines (ulceration or bleeding occurring 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 Tablets 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 Tablets 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 (hypercholesterolaemia)
- are a smoker.

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

NSAIDs including Meloxicam Tablets 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 Tablets 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 Tablets if you are undergoing fertility treatment.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Meloxicam Tablets, 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 month of treatment.
If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Meloxicam Tablets, you must not be re-started on Meloxicam Tablets at any time. **If you develop a rash or these skin symptoms, stop taking Meloxicam Tablets, seek urgent advice from a doctor and tell him that you are taking this medicine.**

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 Tablets or other oxicams (e.g. piroxicam).

Your doctor may want to monitor your liver and kidneys during your treatment with Meloxicam Tablets, 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 Tablets 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 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 or have taken any of the following:
- anticoagulants, (medicines used to stop your blood clotting) such as warfarin, heparin, clopidogrel, dabigatran, apixaban and ticlopidine as Meloxicam can increase their effect or you may be more likely to bleed other non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid (aspirin) or medicines known as 'COX-2 inhibitors' such as celecoxib
- 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
- deferasirox, a medicine used to reduce levels of iron in the body
- mifipristone, used to induce abortions
- zidovudine, used in the treatment of HIV infection
- quinolones, a type of antibiotic
- beta-blockers and calcium channel blockers (medicines used to lower blood pressure) as NSAIDs may reduce their effect
- 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
- pemetrexed, a medicine used to treat certain cancers. You may need to stop taking this medicine for at least 5 days before, during and 2 days after receiving pemetrexed
- 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 Tablets 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 Tablets is therefore not recommended.

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.

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.

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 Tablets may impair female fertility. In women who have difficulties in becoming pregnant or who are undergoing investigations of infertility, withdrawal of Meloxicam Tablets should be considered.

Driving and using machines
Meloxicam Tablets 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 Tablets 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 (23 mg) 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. Check with 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 7.5 mg tablet a day, which may be increased after consultation with your doctor to 15 mg a day (two 7.5 mg tablets or one 15 mg tablet).

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

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Ankylosing spondylitis
One 15 mg tablet per day (or two 7.5 mg tablets).
This may be reduced to one 7.5 mg tablet once a day.
Do **not** exceed the maximum dose of 15 mg 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 7.5 mg per day.

Also, patients at high risk of side effects should start treatment with 7.5 mg a day. If you have severe kidney disease and receive dialysis, the maximum dose of Meloxicam Tablets should be 7.5 mg per day.

Use in children and adolescents
Meloxicam Tablets 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 Tablets is too strong or too weak.

If you take more Meloxicam Tablets 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 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 Tablets
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 for a forgotten dose.

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

4. Possible side effects

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

Stop taking Meloxicam Tablets 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 (pruritus) 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 (pruritus)
- 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 Tablets 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.
- Signs of a heart attack or stroke, which could be caused by a blood clot
  - signs of a heart attack include chest pain that may spread across the upper body or a feeling of tightness of heaviness in the chest, with sweating, nausea (feeling sick), vomiting (being sick) or dizziness
  - signs of a stroke include sudden weakness or numbness of the face, arm or leg, sudden severe headache, sudden changes in speech or confusion, sudden changes in balance, coordination or walking, or a loss of consciousness or seizure (fit)

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)
- 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 looks like round or oval patches of redness and swelling of the skin, blistering (hives), itching.
- female infertility, delayed ovulation

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 printed on the carton and the blister after EXP.
The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original package.

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 Tablets contain
Each Meloxicam Tablets Tablet contains 7.5 mg or 15 mg of the active ingredient Meloxicam Tablets.
The other ingredients are maize starch, pregelatinised starch, colloidal silicon dioxide, sodium citrate, lactose monohydrate, microcrystalline cellulose and magnesium stearate.

What Meloxicam Tablets 7.5 mg look like
Yellow coloured, circular, flat, beveled uncoated tablet with central breakline on one side and plain on the other side.

What Meloxicam Tablets 15 mg look like
Yellow coloured, circular, flat, beveled uncoated tablet with central breakline on one side and plain on the other side.

Tablets are packed in a blister made of PVC/PVDC and aluminium foil, such blisters placed in a carton (Secondary pack).
They are available in blister packs containing 30 tablets.

Marketing Authorisation Holder and Manufacturer
Relonchem Limited,
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Meloxicam Tablets 7.5 mg Tablets - PL 20395/0496
Meloxicam Tablets 15 mg Tablets - PL 20395/0497

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This leaflet was last revised in June 2026.

Code.: DD/DRUGS/DD/752

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