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Meloxicam 7.5mg and 15mg Tablets (POM)

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PHARMA CODE

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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. See section 4.

What is in this leaflet

1. WHAT MELOXICAM TABLET IS AND WHAT IT IS USED FOR

The name of your medicine is Meloxicam 7.5 mg and 15 mg Tablets (referred to as Meloxicam Tablets in this leaflet). Meloxicam Tablet contains the active substance meloxicam which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation and pain in the joints and muscles.
Meloxicam Tablets are indicated for adults and children aged 16 years and over.

Meloxicam Tablets are used for
- the short-term treatment of acute osteoarthritis pain.
- the long-term treatment of rheumatoid arthritis and ankylosing spondylitis (a condition affecting the spine, also known as Bechterew's disease).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MELOXICAM TABLETS

Do not take Meloxicam Tablets:
- during the last three months of pregnancy
- children and adolescents under 16 years of age
- if you are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6)
- if you have had any of the following signs after taking aspirin or other NSAIDs:
  - wheezing, chest tightness, breathlessness (asthma)
  - nasal blockage due to small 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)
- if after previous therapy with NSAIDs you have a history of
  - bleeding in your stomach or intestines
  - holes (perforations) in your stomach or intestines
- ulcers or a bleeding in the stomach or intestines
- a history of stomach or intestinal ulcers or bleeding (ulceration or bleeding occurring at least twice)
- severe hepatic impairment
- severe kidney failure without dialysis
- recent bleeding in the brain (cerebrovascular bleeding)
- bleeding disorders of any type
- severe heart failure
- intolerance to certain sugars since this product contains lactose (see also the paragraph “Meloxicam 7.5 mg and 15 mg Tablets contains lactose”)

If you are unsure whether any of the above apply to you, please contact your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking Meloxicam

Warnings
Medicines such as Meloxicam Tablets 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 doses or the duration of treatment (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 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

Stop your treatment with Meloxicam Tablets immediately as soon as you notice bleeding (causing black 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-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.

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 any other disease of the digestive tract, e.g. ulcerative colitis, Crohn's disease
- 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
- high potassium levels in the blood previously diagnosed by your doctor
- intolerance to certain sugars diagnosed by your doctor, as this product contains lactose

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

Children and adolescents
Meloxicam Tablets are not for use in children and adolescents under 16 years of age.

Other medicines and Meloxicam Tablets
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines obtained without a prescription.

This is especially important if you are taking any of the following:
- other non-steroidal anti-inflammatory drugs (NSAIDs) e.g. aspirin, ibuprofen or naproxen
- potassium salts-used to prevent or treat low blood potassium levels
- trimethoprim-used to treat urinary tract infections
- any medicine used to treat heart problems or high blood pressure e.g. “water tablets” such as bendroflumethiazide, furosemide or digoxin, beta-blockers such as atenolol or for high cholesterol e.g. cholestyramine
- medicines to treat heart and kidney disease
- medicines which prevent blood clotting (anticoagulants) such as warfarin
- medicines which break down blood clots thrombolytics (e.g. heparin)
- tacrolimus, used to prevent and treat the rejection of an organ transplant and also used in immune diseases
- ciclosporin- used after organ transplants, in severe skin conditions, conditions such as rheumatoid arthritis or nephrotic syndrome,
- deferasirox- used to treat iron overload due to frequent blood transfusions
- diuretic medicines, your doctor may need to check your kidney function if you are taking diuretics
- corticosteroids (such as prednisolone, cortisol or cortisone) used to treat inflammation or allergic reactions
- selective serotonin reuptake inhibitors (SSRI's) which are antidepressant medicines (e.g. citalopram, fluoxetine and sertraline), and lithium, used to treat mood disorders
- methotrexate, used to treat some types of cancer, or for psoriasis or rheumatoid arthritis
- pemetrexed-used to treat cancer
- mifepristone, used to induce abortions
- zidovudine, used in the treatment of HIV infection
- quinolones, a type of antibiotic
- if you are a woman who uses a coil (intrauterine contraceptive device (IUD)
- oral antidiabetics (sulfonylureas, nateglinide) – used to treat diabetes. Your doctor should carefully monitor your blood sugar levels for the risk of hypoglycemia.

Laboratory Tests
Tell the doctor if you are due to have a liver or kidney function test.
This is important because taking meloxicam can affect the results.

Meloxicam Tablets with food and drink
Meloxicam Tablets should be swallowed whole with water, or another drink, during a meal.

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
During the first and second trimester of pregnancy, your doctor may prescribe this medicine only if it is essential because it presents a potential risk of miscarriage and malformation. In this case, the dose should be as low as possible, and the duration of treatment as short as possible.

During the last three months of pregnancy, do not use this product, because Meloxicam Tablets can have serious effects on your foetus/child, in particular effects on his heart, lungs and/or kidneys, even with only one administration.

If you have taken this medicine during your pregnancy, you must immediately inform your doctor/midwife so that appropriate monitoring can be considered.

Breast-feeding
This product 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
Do not drive or operate machines until you know how the tablets affect you. They may make you feel light headed, dizzy or drowsy, and may cause blurred vision. If they affect you in any way do not drive or operate machinery

Meloxicam Tablets contain lactose 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 medicinal product contains less than 1 mmol sodium (23 mg) per tablet, i.e. that it is 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 the pharmacist if you are not sure.

The recommended dose is:
Attacks of osteoarthritis:
The recommended dose is 7.5 mg a day. Your doctor may increase your dose to 15 mg a day if necessary.

Rheumatoid arthritis and ankylosing spondylitis:
The recommended dose is 15 mg a day. Your doctor may reduce your dose to 7.5 mg a day if necessary.

Elderly patients and patients with increased risk of side effects:
The recommended dose for treatment of rheumatoid arthritis and ankylosing spondylitis in these patients is 7.5 mg a day.

Patients at increased risk of adverse effects
If you are a patient at increased risk of side effects, your doctor will start your treatment with 7.5 mg daily.

Do not exceed the recommended maximum dose of 15 mg a day.
If any of the statements listed under the heading "Warnings and precautions" apply to you, your doctor may restrict your dose to 7.5 mg (one tablet) once a day.

Patients with kidney impairment:
The maximum recommended dose for treatment in dialysis patients with severe kidney failure is 7.5 mg a day. No dose reduction is necessary in patients with mild to moderate renal impairment.

Hepatic insufficiency
No dose reduction is necessary in patients with mild to moderate hepatic impairment.

Use in children and adolescents
Meloxicam Tablets should not be taken by children and adolescents under 16 years of age.

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

Method of administration
Meloxicam Tablets should be taken by mouth, with a drink of water or other liquid and with food. If you need to take two tablets (7.5mg) they must be taken together as a single dose. The score line is not intended for breaking the tablets.

If you take more Meloxicam Tablets than you should
If you realize you have taken more Meloxicam Tablets than your doctor has recommended (or if someone else has taken some of your Meloxicam Tablets), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

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 a 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 a dose, take it as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking Meloxicam Tablets
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.

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

- Any allergic reaction (hypersensitivity), which may take the form of:
  – Skin reactions, including itching (pruritus), blistering or peeling of the skin, which can be potentially life-threatening rashes (Stevens Johnson syndrome, toxic epidermal necrolysis), soft tissue damage (mucosal damage) or erythema multiforme (see section 2).

Erythema multiforme is a severe allergic reaction of the skin, causing spots, red or purple marks, or bubbles on the surface of the skin. This reaction can also affect the mouth, eyes and other mucous membranes
  – Swelling of tissue under the skin or mucous membranes, for example swelling around the eyes, swelling of the face and lips, mouth or throat, possibly making it difficult to breathe, as well as swelling of the ankles or legs (edema of the legs).
  – Shortness of breath or asthma attack.
  – Inflammation of the liver (hepatitis). This can cause the following symptoms:
    - yellowing of the skin or eyeballs (jaundice),
    - abdominal pain,
    - loss of appetite
- Any adverse effects of the digestive tract, in particular:
  – bleeding (resulting in a black staining of the stools),
  – Ulceration of the digestive tract (resulting in abdominal pain).

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

Tell your doctor immediately if you have previously suffered from such digestive tract symptoms as a result of prolonged use of anti-inflammatory drugs (NSAIDs), especially if you are elderly. Your doctor may need to monitor any changes in your condition during treatment.

If you have vision problems, do not drive or use machinery.

General side effects of nonsteroidal anti-inflammatory drugs (NSAIDs)

The use of certain non-steroidal anti-inflammatory drugs (NSAIDs) may be accompanied, particularly with high doses and in the event of long-term treatment, by a slightly increased risk of occlusion of arterial vessels (arterial thrombotic events), which can cause a heart attack (myocardial infarction) or stroke (apoplexy).

Fluid retention (oedema), increased blood pressure (hypertension) and heart failure have been observed in association with NSAID treatment.

The most commonly observed side effects affect the digestive tract (gastrointestinal events):
- stomach and upper small intestine ulcers (peptic/ gastroduodenal ulcers)
- perforation of the intestinal wall or digestive bleeding (sometimes fatal, especially in the elderly).

The following side effects have been reported after administration of NSAIDs:
- feeling sick (nausea) and vomiting,
- loose stools (diarrhea),
- flatulence,
- constipation,
- indigestion (dyspepsia),
- abdominal pain,
- black stools caused by bleeding in the digestive tract (melena),
- vomiting blood (haematemesis)
- inflammation of the oral mucosa with ulcerations (ulcerative stomatitis),
- worsening of inflammation of the digestive tract (e.g. exacerbation of colitis or Crohn's disease).

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

Other side effects of Meloxicam Tablets

Very common (may affect more than 1 in 10 people)
- 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),
- vertigo or drowsiness (somnolence)
- anemia (reduction in the concentration of hemoglobin, the red blood pigment)
- an increase in blood pressure (hypertension)
- hot flushes (temporary redness of the face and neck),
- increased sodium and water retention
- increased potassium levels (hyperkalaemia), which can lead to symptoms such as changes to your
  - heart rhythm disorders (arrhythmias),
  - palpitations (perception of one's own heartbeats in an exacerbated way),
  - muscle weakness.
- belching
- soreness or inflammation of the mouth (stomatitis),
- inflammation of the stomach (gastritis)
- gastrointestinal bleeding,
- immediate allergic reactions (hypersensitivity)
- itching (pruritus)
- skin rash
- swelling caused by fluid retention (edema), including swelling of the ankles/legs (lower limb edema)
- sudden swelling of tissue under the skin or mucous membranes,such as swelling around the eyes face, lips, mouth or throat, possibly making it difficult to breathe (angioedema)
- 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
  - decrease in the number of white blood cells (leukocytopenia)
  - decrease in the number of blood platelets (thrombocytopenia)

These side effects can lead to an increased risk of infections, as well as symptoms such as bruising or nosebleeds.
- ringing in the ears (tinnitus),
- palpitations,
- stomach or upper small intestine ulcers (peptic/ gastroduodenal ulcers)
- inflammation of the gullet (oesophagitis),
- occurrence of asthma attacks (seen in people who are allergic to aspirin or other NSAIDs),
- severe skin reactions with blistering or peeling of the skin (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- hives,
- vision abnormalities, including:
  – blurred vision,
  – inflammation of the whites of the eyes or eyelids (conjunctivitis),
- inflammation of the large intestine (colitis).

Very rare: may affect up to in 10,000 people
- blistering of the skin (bullous reactions) and erythema multiforme.

Erythema multiforme is a severe allergic reaction of the skin, causing spots, red or purple marks, or bubbles on the surface of the skin. This reaction can also affect the mouth, eyes and other mucous membranes.

inflammation of the liver (hepatitis). This can cause the following symptoms:
  – yellowing of the skin or eyeballs (jaundice),
  – abdominal pain,
  – loss of appetite.
- acute renal failure especially in patients with risk factors such as heart disease, diabetes or kidney disease
- perforation of the intestinal wall.

Not known: frequency cannot be estimated from the available data
- confusion
- disorientation
- shortness of breath and skin reactions (anaphylactic/ anaphylactoid reactions)
- skin rashes caused by exposure to sunlight (photosensitivity reactions)
- heart failure has been reported in association with treatment with NSAIDs,
- Complete loss of a certain type of white blood cell (agranulocytosis), especially in patients taking Meloxicam together with other medicines which may inhibit, depress or destroy bone marrow cells (myelotoxic medicines). This can lead to:
  – a sudden fever,
  – sore throat,
  – infections,
- inflammation of the pancreas (pancreatits),
- 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 the Yellow Card Scheme at: 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.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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

What Meloxicam Tablets look like and the contents of the pack

Meloxicam 7.5mg and 15mg Tablets are yellow, round, flat, uncoated tablets with bevelled edges. They are scored on one side and plain on the other side.

They are available in blister packs containing 10, 30 or 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder
Flamingo Pharma (UK) Ltd.
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