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PATIENT INFORMATION LEAFLET

Meloxicam 7.5MG and 15MG Tablets

Read all of this leaflet because it contains important information for you.
- *Keep this leaflet. You may need to read it again.*
- *Ask your pharmacist if you need more information or advice.*
- *You must see a doctor if your symptoms worsen or do not improve.*
- *This medicine is prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.*

In this leaflet:

1. **What Meloxicam is and what it is used for**
2. **Before you take Meloxicam**
3. **How to take Meloxicam**
4. **Possible side effects**
5. **Storing Meloxicam**

The name of your medicine is Meloxicam 7.5mg or 15mg Tablets (referred to as Meloxicam in this leaflet).

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

Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are used to reduce inflammation and pain in joints and muscles.
Meloxicam is used to treat short term bouts of osteoarthritis, and long term for rheumatoid arthritis and ankylosing spondylitis.

2. BEFORE YOU TAKE MELOXICAM

Do not take Meloxicam:
- **If you are allergic to meloxicam, to aspirin or to other NSAID's**, or to any of its ingredients
- **If you have developed signs of asthma (wheezing),** nasal polyps (nasal obstruction) along with runny nose, swelling of the skin or rash when taking aspirin or other NSAIDs
- **If you have an active or a history of recurrent peptic ulcers (more than two).**
- **If you have a history of gastrointestinal bleeding or perforatlon related to the use of NSAIDSs.**
- **If you have severe liver disease**
- **If you have severe renal failure** and are not undergoing dialysis
- **If you have bleeding disorders** e.g. gastrointestinal or of the brain
- **If you have severe uncontrolled heart failure**
- **during the last trimester of pregnancy or If you are planning to become pregnant or breast feeding.**

Take special care and tell your doctor or pharmacist before taking this medicine
- If you have high blood pressure or any liver, kidney or heart problems.
- If you have a history of gastrointestinal disease e.g. inflammation of the stomach (gastritis) or gullet (oesophagitis), ulcer, ulcerative colitis, Crohn's disease.
- If you are elderly
- If you have systemic lupus erythematous (SLE) and mixed connective tissue disorders
- If you have or have had bronchial asthma
- If you have undergone recent surgery
- If you are taking any other medicines including any bought without a prescription.
- If you are a women who uses an intrauterine contraceptive device (IUD) usually known as a coli.

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Warnings
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 or duration of treatment. If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Talk to your doctor or pharmacist before taking Meloxicam:
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).

Taking Meloxicam with food and drink
Take the total dose by mouth with a drink of water or other liquid during a meal.

Pregnancy and breast-feeding
Meloxicam 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.

Important information about some of the ingredients
If your doctor has told you that you have an in tolerance to some sugars, contact your doctor before taking this medicine.

Driving and using machines
If you experience blurred vision, dizziness or tiredness whilst taking Meloxicam, avoid driving or operating machinery.

Taking/using other medicines
Inform your doctor or pharmacist if you are taking any other medicines before you take Meloxicam, particularly any of the following:
- Other anti-inflammatory drugs, including aspirin
- Medicines which prevent blood clotting such as warfarin
- Medicines which break down blood clots (thrombolytics)
- Any diuretics medicine ("watertablets")
- Medicines to treat high blood pressure
- Ciclosporin, used following organ transplantation and other immune diseases
- Glucocorticoids, generally used as an anti-inflammatory
- Lithium, used to treat certain mental illnesses
- Methotrexate, used to treat cancer and other immune disorders
- Colestyramine. used to treat high choleslerol and itching which occurs with jaundice and other conditions
- Selective Serotonin re-uptake inhibitors used in the treatment of depression
- Cardiac glycosides, drugs used in the treatment of congestive heart failure and cardiac arrhythmia.
- Zidovudine, drug used for the treatment of AIDS and HIV infection
- Tacrolimus, an immunosuppressive drug used to reduce the activity of the immune system
- Quinolones, synthetic broad-spectrum antibiotics
- Mifepristone, used as an abortifacient and emergency contraceptive

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine even those not prescribed.

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3. HOW TO TAKE MELOXICAM

Your doctor has prescribed this medicine for you and you must follow your doctor's instructions. Always read the label. If you do not understand these instructions or are in any doubt, ask your doctor or pharmacist.

- Take with or after food.
- Meloxicam tablets are for oral use.
- Depending on the condition you have, **the usual dosage is 7.5mg or 15mg taken daily** with a drink of water or other liquid during a meal.
- If you need to take two tablets they must be taken together as a single dose
- If after several days you do not feel any improvement in your condition you should talk to your doctor

Meloxicam is not recommended for children under 15 years of age.

Do not take more than 15mg in a day.
If you take more Meloxicam than you should, contact your doctor or nearest hospital casualty department immediately.

If you forget to take MeloxIcam
Do not take a double dose to make up for the forgotten dose. Take your next dose as usual. If you are not sure speak to your pharmacist or doctor.

4. POSSIBLE SIDE EFFECTS

If you experience any of the following symptoms, stop the treatment and seek medical advice immediately

Rarely meloxicam may cause facial swelling, swelling of the blood vessels in the skin and severe skin reactions such as large fluid-filled blisters, sores and ulceration, and shortness of breath. Ulceration can also occur in the mouth and throat, around the anus and genital region and on the surface of the eyes. These symptoms are often accompanied by sickness, headache and lever.

The skin may become more sensitive to sunlight.

A few people have allergic reactions to medicines. If you develop any of the following symptoms stop taking meloxicam and seek medical advice **Immediately:**

- Sudden wheeziness, difficulty breathing or tightness in the chest
- Swelling of the eye-lids, face or lips
- Skin lumps or red, itchy spots
- Itch all over the body
- Pancreatitis (inflammation of the pancreas)

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.
- STOP TAKING the medicine and tell your doctor if you experience: Indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

All medicines can cause side effects. Meloxicam may cause the following:

Medicines such as meloxicam may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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Side effects that are common:
Feeling lightheaded, headache, feeling or being sick, anaemia, pain in the abdomen, wind, constipation, diarrhoea, itching or rash, swelling in the legs.

Uncommon side effects include:
Feeling tired, dizzy, tinnitus (ringing in the ears), drowsiness, gastrointestinal bleeding (black or tarry stools), stomach ulcers, inflammation of the gullet or mouth, small areas of swelling or wheals, giddiness (vertigo), abnormal heartbeats (palpitations), increased blood pressure or flushes. Occasionally the results of liver, kidney and blood tests may be abnormal.

Rare side effects
Changes in mood, sleeplessness, nightmares, confusion, disturbances of vision such as blurring, perforation of the gut (holes in the wall of the gut), inflammation of the stomach or the lower part of the gut (colon), inflammation of the liver, renal failure or onset of asthma in patients allergic to aspirin or other NSAIDs.

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

If you have these or any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

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. STORING MELOXICAM TABLETS

Keep out of reach and sight of children.
Do not store above 25° C.
Do not use after the expiry date printed on the pack.
Return all unused medicines to your pharmacist for safe disposal.

6. FURTHER INFORMATION

This leaflet does not contain all the information on Meloxicam. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Each tablet contains either 7.5mg or 15mg of the active ingredient meloxicam. The tablet also contains maize starch, pregelatinised starch, colloidal silica, sodium citrate, lactose monohydrate, microcrystalline cellulose and magnesium stearate.

What this medicine looks like and contents of the pack:
Meloxicam tablets are yellow, round, uncoated tablets and are supplied in blister packs containing 10, 30 or 100 tablets in a carton.

Marketing authorisation Holder:
Somex Pharma, High Road, Ilford, Essex, IG3 8BS, UK

Manufacturer:
Somex Pharma, High Road, Ilford, Essex, IG3 8RA, UK

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