PACKAGE LEAFLET: INFORMATION FOR THE USER
Meloxicam 15 mg Orodispersible Tablets

Meloxicam 15.0 mg

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for **you.** Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. WHAT MELOXICAM ORODISPERSIBLE TABLETS ARE AND WHAT THEY ARE USED FOR

Meloxicam tablets belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which can be used to reduce inflammation and pain in joints and muscles. (Orodispersible tablets are tablets which dissolve easily in the mouth).
Meloxicam tablets are used for:
- the short-term treatment of the symptoms of acute attacks of osteoarthritis;
- the long-term treatment of the symptoms of:

- rheumatoid arthritis,
- ankylosing spondylitis (a disease of the backbone).

2. BEFORE YOU TAKE MELOXICAM TABLETS

Do not take Meloxicam tablets **and tell your doctor if you:**
- are allergic to Meloxicam or to any of the other ingredients (See section 6 for a list of these);
- are pregnant, planning to become pregnant or if you are breast-feeding;
- are allergic to aspirin or to other non-steroidal anti-inflammatory medicines (NSAIDs);
- have ever developed signs of asthma (wheezing), nasal polyps along with a runny nose, swelling of the skin or nettle-rash, when taking aspirin or other anti-inflammatory medicines;
- have or have ever had an ulcer of the stomach or intestines;
- have any kind of bleeding disorder or have ever suffered from bleeding in the stomach or intestines or bleeding in the brain;
- have severe liver disease;
- have severe kidney failure and are not receiving dialysis;
- suffer from severe heart failure.
- have a galactose intolerance, the Lapp-lactose deficiency or glucosegalactose malabsorption.
- have Crohn´s disease
- have ulcerative colitis
- suffer from pain after coronary artery bypass

If you think any of these apply to you, do not start taking these Meloxicam tablets. **Talk to your doctor first** and follow the advice given to you.

Take special care with Meloxicam tablets
Tell your doctor or pharmacist **before** taking this medicine:
- if you have high blood pressure;
- if you have heart, liver or kidney disease;
- if you have diabetes;
- if you are elderly (65 years old or more);
- if you have an inherited illness called phenylketonuria, because this medicine contains aspartame (E951);
- if you have been told that you have intolerance to some sugars, because this medicine contains sorbitol (E420), a kind of sugar,
- if you have a reduced volume of blood in your body, which may occur if you have serious blood loss or burns, surgery or low fluid intake;
- if you have ever been diagnosed with high potassium levels in the blood;

Tell your doctor if you think any of these apply to you.

Warning
Medicines such as these Meloxicam tablets may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
Discuss your treatment with your doctor or pharmacist if you have heart problems, have previously had a stroke or you think you might be at risk of conditions such as high blood pressure, diabetes or high cholesterol, or if you are a smoker.

Taking other medicines
When you are taking Meloxicam tablets, do not take any other medicines – including medicines obtained without a prescription – without first talking to your doctor or pharmacist.
Tell your doctor or pharmacist if you are taking **any** of the following medicines:
- **any other** non-steroidal anti-inflammatory drugs (NSAIDs), **including aspirin;**
- medicines to prevent blood clotting, such as warfarin;
- medicines to break down blood clots;
- medicines to treat high blood pressure;
- oral corticosteroids;
- cyclosporin;
- any diuretic medicine (your doctor may 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;
- colestyramine;
- you use an intrauterine contraceptive device (IUD), usually known as a coil.

Pregnancy and breast-feeding
Meloxicam tablets are **not** recommended for use by women who are pregnant or breast-feeding.
Tell your doctor **immediately** if you are pregnant, think you may be pregnant, or if you are breast-feeding.
Ask your doctor or pharmacist for advice before using any medicine.

Children (under 16 years old)
This medicine **must not** be given to children under 16 years old.

Driving and using machinery
Do not drive or operate machinery until you know how Meloxicam tablets affect you. If the tablets make you feel light-headed, dizzy or drowsy, or cause blurred vision, **do not** drive or operate machinery.

Important information about some of the ingredients of Meloxicam tablets
- These tablets contain the sweetener aspartame (E951), a source of phenylalanine. Contact your doctor **before** taking them if you have an inherited illness called phenylketonuria.
- These tablets contain sorbitol (E420), a kind of sugar. If you have ever been told you have intolerance to some sugars, contact your doctor **before** taking these tablets.

3. HOW TO TAKE MELOXICAM TABLETS

Always take Meloxicam tablets exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure. Read the label carefully.
Taking this medicine
- Place the tablet in your mouth on your tongue.
- allow it to dissolve, slowly for five minutes (It must never be chewed or swallowed undissolved)
- swallow with a drink of 240 ml of water.
- If you have a dry mouth, use water to moisten it first.
- **Never** take more than the recommended maximum dose of

15 mg (one tablet) a day.

Dosage
The dose depends on the medical condition which is being treated. Your doctor will let you know how much you should take.

For the treatment of acute attacks of **osteoarthritis:**
The usual dose is 7.5 mg (half a tablet) a day. Your doctor may increase your dose to 15 mg (one tablet) a day, if necessary.

For the treatment of **rheumatoid arthritis and ankylosing spondylitis:**
The usual dose is 15 mg (one tablet) a day. Your doctor may reduce your dose to 7.5 mg (half a tablet) a day if necessary.
If you are **aged 65 years and over,** the recommended dose for the long term treatment of rheumatoid arthritis and ankylosing spondylitis is 7.5 mg (half a tablet) a day.

If you have any of the conditions listed in Section 2 under the heading "Take special care with Meloxicam tablets", your doctor may restrict your dose to 7.5 mg (half a tablet) a day.

If you feel that the effect of these Meloxicam tablets is too strong or too weak, or after several days you do not feel any improvement in your condition, consult your doctor or pharmacist.

If you take more of this medicine than you should
Contact your doctor or pharmacist **immediately** or go **immediately** to the accident and emergency department of your nearest hospital, taking this leaflet or the tablets with you.

If you forget to take your tablet (or half tablet)
Never take two doses on the same day to make up for one you have missed.
Take your usual dose the next day.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Meloxicam tablets can cause side effects, although not everybody gets them.
- If you have a history of gastrointestinal symptoms while taking anti inflammatory drugs, your doctor may monitor your progress while you are having this treatment.

Clinical trials and scientific data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of blood clots in the arteries (which could, for example, lead to heart attack or stroke).

Contact your doctor immediately, or go immediately to the accident and emergency department of your nearest hospital, (taking this leaflet or the tablets with you), if you get the following serious side effects**:**

- severe allergic reactions which may include fainting, shortness of breath, skin reactions and asthma attacks (common side effect: affects 1 to 10 users in 100);
- bleeding in the stomach or intestines, peptic ulcers, soreness or inflammation of the mouth, or inflammation of the gullet (uncommon side effect: affects 1 to 10 users in 1,000);
- severe blistering or peeling of the skin, swelling around the eyes, lips and face, rashes caused by exposure to sunlight (rare side effect: affects 1 to 10 users in 10,000).

Contact your doctor if you get the following side effects**:**
Pancreatitis (inflammation of the pancreas)

Common side effects (affects 1 to 10 users in 100):
- indigestion, feeling or being sick, abdominal pain, constipation, flatulence, diarrhoea; skin rashes or itching;
- light-headedness, headaches;
- swelling of ankles and legs;
- anaemia.

Uncommon side effects (affects 1 to 10 users in 1,000):
- hypersensitivity;
- nettle rash or hives;
- dizziness, tinnitus, drowsiness;
- irregular heart beat, increased blood pressure, hot flushes;
- abnormal white blood cell or platelet numbers;
- changes to liver function;
- salt and water retention, excessive potassium, changes to kidney function.

Rare side effects (affects 1 to 10 users in 10,000):
- a hole in the bowel wall, inflammation or soreness of the stomach or intestines (ulcers of the stomach or intestines, bleeding and perforations in the stomach or intestines can occur at any time, can some times, especially in the elderly, be severe and could, very rarely, in fewer than 1 in every 10,000 patients treated, be fatal);
- confusion, mood swings, insomnia, nightmares;
- visual disturbances such as blurred vision;
- inflammation of the liver (hepatitis);
- kidney failure.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard
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 reach and sight of children.
- Do not transfer the tablets to another container.
- This product does not require any other special storage requirements in EU countries.
- Do not use Meloxicam 15 mg orodispersible tablets after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.

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. FURTHER INFORMATION

What Meloxicam 15 mg orodispersible tablets contain
The **active** ingredient is Meloxicam.
Each tablet contains 15mg.
The **other** ingredients are mannitol (E421), aspartame (E951), sorbitol (E420), citric acid anhydrous (E330), yoghurt flavour, forest fruit flavour, povidone (E1201), talc (E553b), sodium lauryl sulfate and magnesium stearate (E572).

What Meloxicam tablets look like and contents of the pack
Meloxicam 15 mg tablets are round light yellow, flat, scored tablet embossed with AX5 on one side, which can be divided into equal halves. . The tablets are supplied in:
- Boxes containing 2 blister packs of 10 tablets each,
- Boxes containing 3 blister packs of 10 tablets each,
- Boxes with one polyethylene bottle with polypropylene child-resistant tamper-evident screw cap with desiccant containing 30 tablets each.
- Boxes with one polyethylene bottle with polypropylene child-resistant tamper-evident screw cap with desiccant containing 200 tablets each.

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This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria & Poland: Trosicam
Czech Republic: Oramellox 15 mg
Greece & Republic of Cyprus: Meloxicam /Medical
Hungaria: Trosicam 15 mg szájban diszpergálódó tabletta
Romania: Trosicam 15 mg comprimate orodispersible
Slovakia: Oramellox 15 mg
UK: Meloxicam 15 mg Orodispersible Tablets

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