

PACKAGE LEAFLET: INFORMATION FOR THE USER**Meloxicam 7.5 mg Orodispersible 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, please 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

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1. What Meloxicam 7.5 mg orodispersible tablets is and what it is used for

Meloxicam 7.5 mg orodispersible 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).

You must talk to a doctor if you do not feel better or if you feel worse after 20 days in case of short-term treatment.

2. What you need to know before you take Meloxicam 7.5 mg orodispersible tablets**Do not take Meloxicam 7.5 mg orodispersible tablets if you:**

- are allergic to Meloxicam or to any of the other ingredients of this medicine (listed in section 6);
- 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 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Meloxicam 7.5 mg orodispersible tablets.

Take special care with Meloxicam 7.5 mg orodispersible 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.

Children and adolescents

This medicine **must not** be given to children and adolescent under 16 years old.

Other medicines and Meloxicam 7.5 mg orodispersible tablets

Tell your doctor or pharmacist if you are taking , have recently taken or might take any 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

Do not take Meloxicam 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 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 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.

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.

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.

Driving and using machines

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.

Meloxicam 7.5 mg orodispersible tablets contains mannitol, aspartame and sorbitol

- Mannitol may have a mild laxative effect.
- This medicine contains 4 mg aspartame in each dosage unit. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Contact your doctor **before** taking them if you have an inherited illness called phenylketonuria.
- This medicine contains 20 mg sorbitol in each dosage unit. If you have ever been told you have intolerance to some sugars, contact your doctor **before** taking these tablets.

3. How to take Meloxicam 7.5 mg orodispersible tablets

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

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 (two tablets) 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.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

Check with your doctor or pharmacist if you are not sure.

For the treatment of acute attacks of **osteoarthritis**:

The recommended dose is 7.5 mg (one tablet) a day. Your doctor may increase your dose to 15 mg (two tablets) a day, if necessary.

For the treatment of **rheumatoid arthritis and ankylosing spondylitis**:

The recommended dose is 15 mg (two tablets) a day. Your doctor may reduce your dose to 7.5 mg (one 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 (one tablet) a day.

If you have any of the conditions listed in Section 2 under the heading “Take special care with Meloxicam 7.5 mg orodispersible tablets”, your doctor may restrict your dose to 7.5 mg (one 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 Meloxicam 7.5 mg orodispersible tablets 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 Meloxicam 7.5 mg orodispersible tablets**Do not take a double dose to make up for a forgotten dose**

Take your usual dose the next day.

If you stop taking Meloxicam 7.5 mg orodispersible 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.

- 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 sometimes, 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 7.5 mg orodispersible tablets

- Keep this medicine out of the sight and reach 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 this medicine after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information**What Meloxicam 7.5 mg orodispersible tablets contains**

The **active** ingredient is Meloxicam.

Each tablet contains 7.5 mg.

The **other** ingredients are mannitol (E421), aspartame (E951), sorbitol (E420), citric acid anhydrous (E330), yoghurt flavour (nature identical flavouring substances, flavouring preparations, natural flavours, maize maltodextrin, glycerol triacetate EP), forest fruit flavour (nature identical flavouring

substances, flavouring preparations, natural flavours, maize maltodextrin, glycerol triacetate EP, modified starch), povidone K30 (E1201), crospovidone (E1202), talc (E553b), sodium lauryl sulfate and magnesium stearate (E572).

What Meloxicam 7.5 mg orodispersible tablets look like and contents of the pack

Meloxicam 7.5 mg tablets is a round light yellow, flat tablet (200 mg/ tbl, diameter 9 mm) embossed with AX6 on one side.

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

This leaflet was last approved in ...