

MELOXIAURO™ 7.5 & 15

Meloxicam 7.5 mg and 15 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MELOXIAURO. It does not contain all available information, nor does it take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking MELOXIAURO against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again later.

What MELOXIAURO is used for

MELOXIAURO is used to treat the symptoms of:

- osteoarthritis; and
- rheumatoid arthritis.

Both diseases mainly affect the joints causing pain and swelling.

Although MELOXIAURO can relieve the symptoms of pain and inflammation, it will not cure your condition.

MELOXIAURO belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

Ask your doctor if you have any questions about why MELOXIAURO has been prescribed for you.

Your doctor may have prescribed MELOXIAURO for another reason.

Before you take it

When you must not take it

Do not take MELOXIAURO if you have an allergy to:

- any medicine containing meloxicam;
- the active ingredient, meloxicam, or any of the other ingredients in MELOXIAURO (all of these ingredients are listed at the end of this leaflet); or
- aspirin or any other NSAIDs.

Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body; or
- rash, itching or hives on the skin.

Ask your doctor if you are unsure if you are allergic to these ingredients.

Do not take MELOXIAURO if:

- you are about to undergo coronary artery bypass graft surgery;
- you have a disease of the heart with shortness of breath, and swelling of the feet or lips due to fluid build-up;
- you experience bleeding from the stomach, gut or any other bleeding;
- you have had a stroke resulting from a bleed in the brain or have a bleeding disorder;
- you have a galactose intolerance;
- you currently have a peptic (stomach) ulcer;

- you have had inflammation of the lining of the stomach or bowel (e.g. Crohn's Disease or Ulcerative Colitis);
- you have severe liver or kidney problems; or
- you are currently taking other medicines known as: sulfinpyrazone (used to treat gout), fluconazole (used to treat fungal infections) or certain sulfur antibiotics (e.g. sulfaphenazole or sulfamethoxazole).

Do not breast-feed if you are taking this medicine.

The active ingredient in MELOXIAURO passes into breast milk and there is a possibility that your baby may be affected.

Do not give MELOXIAURO to children and adolescents under 18 years of age. Safety and effectiveness in children younger than 18 years have not been established.

Do not take MELOXIAURO after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking MELOXIAURO, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, food, preservative or dyes.

You must tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- high blood pressure or fluid retention;
- diabetes;
- high cholesterol;
- heartburn, indigestion, ulcers or other stomach problems;
- kidney or liver disease; or
- asthma or any other breathing problems.

Tell your doctor if you are pregnant, planning to become pregnant or are using an IUD for birth control.

Your doctor will discuss the risks and benefits of taking it during pregnancy.

Tell your doctor if you currently have an infection.

MELOXIAURO may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MELOXIAURO.

Taking other medicines

Before taking MELOXIAURO, tell your doctor or pharmacist if you are taking any other medicines, including medicines that you get without a prescription from your pharmacy, supermarket or health food shop.

There may be interference between MELOXIAURO and some medicines. These include:

- aspirin, salicylates or other NSAIDs;

- medicines used to thin your blood (such as warfarin, heparin and ticlopidine);
- medicines used to treat high blood pressure and other heart problems such as ACE inhibitors, angiotensin receptor antagonists and diuretics (also called fluid or water tablets);

When taken together these medicines can cause kidney problems.

- lithium, a medicine used to treat some types of depression;
- antidepressants called selective serotonin reuptake inhibitors (SSRIs);
- methotrexate, a medicine used to treat rheumatoid arthritis (a painful joint disease) and some types of cancer;
- cyclosporin, a medicine used to treat rheumatoid arthritis and certain problems with the immune system;
- terfenadine and astemizole, medicines used to prevent or relieve the symptoms of allergy, such as hay fever or insect stings;
- medicines to treat diabetes;
- cholestyramine, a medicine used to treat high cholesterol levels in the blood;
- corticosteroids, medicines usually used to treat inflammatory conditions, such as skin rashes and asthma;
- some medicines used to treat infections (e.g. erythromycin, sulfur antibiotics, ketoconazole, itraconazole);
- some medicines used to treat irregular heartbeats (e.g. amiodarone and quinidine); or
- pemetrexed, a medicine used in the treatment of certain lung cancers.

These medicines may be affected by MELOXIAURO or may affect how well it works. You may need different amounts of your medicines, or you may need different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MELOXIAURO.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

For the treatment of osteoarthritis

The usual dose of MELOXIAURO is 7.5 mg, taken as a single dose each day.

Depending on the severity of your condition and your response to treatment, your doctor may increase this dose to 15 mg taken as a single dose each day.

For the treatment of rheumatoid arthritis

The usual dose of MELOXIAURO is 15 mg taken as a single dose each day.

Depending on your response, your doctor may reduce the dose to 7.5 mg taken as a single dose each day.

The maximum recommended daily dose of MELOXIAURO is 15 mg.

For patients with kidney problems undergoing dialysis, the maximum recommended daily dose is 7.5 mg.

Ask your doctor for more information if you have been advised to take a different dose.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Try to take MELOXIAURO at the same time each day, either morning or evening. Taking MELOXIAURO at the same time each day will have the best effect. It will also help you remember when to take it.

Take your medicine with or straight after food.

This may help reduce the possibility of stomach upset.

How long to take it

Continue taking MELOXIAURO for as long as your doctor tells you.

MELOXIAURO helps control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose (e.g. within 2-3 hours), skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you have taken too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much MELOXIAURO. Do this even if there are no signs of discomfort or poisoning.

Signs of an overdose with MELOXIAURO may include:

- nausea and/or vomiting;
- headache;
- drowsiness and/or dizziness;
- blurred vision;
- fits or seizures;
- low blood pressure;
- difficulty in breathing;
- impaired consciousness; or
- kidney failure.

While you are taking it

Things you must do

If you are about to start any new medicines, remind your doctor and pharmacist that you are taking MELOXIAURO.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking MELOXIAURO.

MELOXIAURO can slow down blood clotting.

If you become pregnant while taking MELOXIAURO, tell your doctor immediately.

If you get an infection while using MELOXIAURO, tell your doctor.

MELOXIAURO may hide some of the signs of an infection (e.g. pain, fever, redness and swelling). You may think, mistakenly, that you are better or that the infection is not serious.

Things you must not do

Do not take MELOXIAURO to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how MELOXIAURO affects you.

As with other NSAID medicines, MELOXIAURO may cause dizziness, drowsiness or blurred vision in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MELOXIAURO.

This medicine helps most people but it may have unwanted side effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Check with your doctor as soon as possible if you have any problems while taking MELOXIAURO, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset including nausea, vomiting, heartburn, indigestion, belching, cramps or pain;
- headache;
- flu-like symptoms, runny or blocked nose, cough, sore mouth or throat, discomfort when swallowing;
- constipation, diarrhoea or wind;
- dizziness or light-headedness;
- skin rashes, which may be caused by exposure to sunlight, can blister and may take on the appearance of a severe burn, or itching;
- increase in blood pressure; or
- tinnitus (ringing in the ear).

The above list includes the more common side effects of your medicine. These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision;
- any change in the amount or colour of your urine (red or brown) or any pain or difficulty experienced when urinating;
- collapse or fainting, shortness of breath or tiredness, fast or irregular heartbeat (also called palpitations), chest pain, swollen or sore leg veins;
- severe dizziness;
- severe pain or tenderness in the stomach;
- flaking of the skin;
- yellowing of the skin and eyes (known as jaundice);
- swelling of your ankles, legs or other parts of your body;
- signs of anaemia (such as tiredness, being short of breath and looking pale); or
- irritation of your mucous membranes (e.g. lips, mouth, eyes or genitals).

These are rare but serious side effects. You may need urgent medical attention.

If any of the following happens, STOP taking MELOXIAURO and tell your doctor immediately or go to Emergency at your nearest hospital:

- vomiting of blood or material that looks like coffee grounds;
- bleeding from your back passage (rectum), black sticky motions (stools) or bloody diarrhoea;
- swelling of the face, lips or tongue which may make swallowing or breathing difficult;
- asthma, wheezing or shortness of breath;
- sudden or severe itching, skin rash or hives; or
- weakness in one part or side of your body, slurred speech, blurred vision or visual disturbances.

These are rare but very serious side effects. You may need urgent medical attention or hospitalisation.

Not all of these side effects have been reported with MELOXIAURO but have been seen with similar medicines.

Other side effects not listed above may occur in some people.

Tell your doctor if you notice anything else that is making you feel unwell.

After taking it

Storage

Keep your tablets in their pack until it is time to take them.

If you take them out of their packaging, they will not keep well.

Keep MELOXIAURO in a cool dry place where the temperature stays below 25°C and protected from light.

Do not store MELOXIAURO in the bathroom or near a sink. Do not leave it on a window sill or in a car.

Heat and dampness can destroy some medicines.

Keep your tablets where children cannot reach them.

A locked cupboard at least one-and one-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MELOXIAURO (7.5 & 15 mg meloxicam) is presented in blister packs* of 30 or 60 tablets.

MELOXIAURO 7.5 (AUST R 188881)

Light yellow, round, uncoated tablet with score line between 'F' and '1' debossed on one side and plain on the other side.

MELOXIAURO 15 (AUST R 188878)

Light yellow, round, uncoated tablet with score line between 'F' and '2' debossed on one side and plain on the other side.

Ingredients

Active Ingredient:

Meloxicam

Each tablet may contain either 7.5 mg or 15 mg of meloxicam.

Other Ingredients:

- sodium citrate;
- lactose;
- microcrystalline cellulose;
- povidone;
- crospovidone;
- colloidal anhydrous silica; and
- magnesium stearate.

MELOXIAURO does not contain gluten or sucrose.

*Some of these pack sizes are not marketed.

Sponsor/Marketing Authorisation Holder

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