

APO-MELOXICAM

Meloxicam

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about meloxicam. It does not contain all the available information. It does not 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 meloxicam 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.

What this medicine is used for

Meloxicam is used to treat the symptoms of osteoarthritis and rheumatoid arthritis. These conditions mainly affect the joints, causing pain and swelling.

How it works

Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain and inflammation.

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

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- meloxicam
- aspirin or any other NSAIDs
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

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

Do not take this medicine if you have any of the following medical conditions:

- coronary artery bypass graft surgery
- heart disease with shortness of breath, and swelling of limbs due to fluid build-up
- bleeding disorder, including from the stomach or gut

- stroke resulting from a bleed in the brain
- galactose intolerance
- peptic (stomach) ulcer
- inflammation of the lining of the stomach or bowel (e.g. Crohn's disease or ulcerative colitis)
- severe liver or kidney problems
- are currently taking the following medicines: fluconazole (used to treat fungal infections) or certain sulfur antibiotics (e.g. sulfamethoxazole).

Do not take this medicine if you are pregnant, or think you may be pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

Meloxicam may pass into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine 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 this medicine, 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.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease
- high blood pressure
- fluid retention

- diabetes
- high cholesterol
- serious skin reactions, such as Stevens-Johnson syndrome, toxic epidermal necrosis or exfoliative dermatitis
- heartburn, indigestion, ulcers or other stomach problems
- kidney or liver disease
- asthma or any other breathing problems.

Tell your doctor if you are pregnant, plan to become pregnant or are using an IUD (intrauterine device) for birth control.

Meloxicam is not recommended for use during pregnancy. If there is a need to consider meloxicam during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

NSAID medicines, like meloxicam, may also decrease the effectiveness of IUDs.

Tell your doctor if you have an infection.

Meloxicam 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 this medicine.

Taking other medicines

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

Some medicines and meloxicam may interfere with each other. These include:

- aspirin, salicylates or other NSAIDs
- medicines used to thin your blood (e.g. warfarin, heparin and ticlopidine)
- medicines used to treat high blood pressure and other heart problems (e.g. ACE inhibitors, angiotensin receptor antagonists and diuretics). When taken

together these medicines can cause kidney problems.

- lithium, used to treat some types of depression
- antidepressants called selective serotonin reuptake inhibitors (SSRIs)
- methotrexate, used to treat rheumatoid arthritis and some types of cancer
- pemetrexed, used to treat some types of lung cancer
- cyclosporin, used to treat rheumatoid arthritis and certain immune system problems
- terfenadine and astemizole, used to prevent or relieve the symptoms of allergy
- type of contraceptive known as an IUD
- medicines to treat diabetes
- cholestyramine, used to treat high cholesterol levels
- corticosteroids, used to treat inflammatory conditions, such as skin rash 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)

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Osteoarthritis

The usual dose of meloxicam is one 7.5 mg tablet taken once a day.

Your doctor may increase this dose to one 15 mg tablet taken once a day if needed.

Rheumatoid arthritis

The usual dose of meloxicam is one 15 mg tablet taken once a day.

Your doctor may reduce this dose to one 7.5 mg tablet taken once a day.

The maximum recommended daily dose of meloxicam is 15 mg.

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

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it 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 after food.

This may help reduce the possibility of stomach upset.

How long to take it

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

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, and 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.

This may increase the chance of side effects.

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

If you take too much (overdose)

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

You may need medical attention.

Symptoms of an overdose may include:

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

While you are taking this medicine

Things you must do

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

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 this medicine.

Meloxicam can slow down blood clotting.

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

Tell your doctor if you get an infection while taking this medicine.

Meloxicam may hide some of the signs of an infection, such as pain,

fever, redness and swelling. You may think, mistakenly, that you are better or that the infection is not serious.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine 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 meloxicam affects you.

This medicine 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 this medicine.

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.

Not all of the following side effects have been reported with meloxicam but have been seen with similar medicines.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist 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
- increase in blood pressure
- tinnitus (ringing of 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 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 pain or tenderness in the stomach
- severe dizziness
- yellowing of the skin and eyes (known as jaundice)
- flaking of the skin
- swelling of your ankles, legs or other parts of your body
- signs of anaemia (such as tiredness, being short of breath and looking pale)

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

If any of the following happen, stop taking your medicine and tell your doctor immediately or go to Accident and 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
- weakness in one part or side of your body, slurred speech, blurred vision or visual disturbances
- flu-like symptoms, followed by irritation of your mucous membranes (e.g. lips, mouth, eyes or genitals) and a painful red or purplish rash that spreads and blisters.

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

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

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

Storage and Disposal

Storage

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

If you take them out of the pack, they will not keep well.

Keep your medicines in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-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

7.5 mg tablets

Pale-yellow, circular, flat bevelled tablets with a central break-line on one side and plain on the other side. AUST R 309142.

Available in blister packs of 30 tablets.

15 mg tablets

Pale-yellow, circular, flat beveled tablets with a central break-line on one side and plain on the other side. AUST R 309141.

Available blister packs of 30 tablets.

Ingredients

This medicine contains 7.5 mg or 15 mg of meloxicam as the active ingredient.

This medicine also contains the following:

- lactose monohydrate
- maize starch
- sodium citrate dihydrate
- colloidal anhydrous silica
- magnesium stearate
- microcrystalline cellulose
- pregelatinised maize starch

This medicine does not contain gluten or sucrose.

Sponsor

Apotex Pty Ltd
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