

APO-Meloxicam

Capsules

Meloxicam

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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 using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Meloxicam. It contains the active ingredient meloxicam.

It is used to treat the symptoms of

- osteoarthritis
- rheumatoid arthritis

Both diseases mainly affect the joints causing pain and swelling.

Although meloxicam can relieve symptoms such as 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 this medicine for another reason.

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

How it works

Meloxicam belongs to a family of medicines called Non-Steroidal Anti-inflammatory Drugs (NSAIDs).

These medicines work by relieving pain and inflammation.

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not take it

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

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

Do not take this medicine if:

- You are about to undergo a 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 currently have a peptic (stomach) ulcer
- You are lactose intolerant (this medicine contains lactose)
- You have Crohn's Disease or Ulcerative Colitis

- You have severe liver or kidney problems
- 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 breastfeed if you are taking this medicine

Meloxicam may pass into breast milk and affect your baby.

Do not give meloxicam 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 this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should be taking this medicine, talk to your doctor.

Before you start to take it

Before you start taking this medicine, tell your doctor if you have allergies to any other medicines, food, preservatives or dyes.

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

- high blood pressure or fluid retention
- diabetes
- high cholesterol or other risk factors for heart disease
- heartburn, indigestion, ulcers or other stomach problems
- kidney or liver disease
- asthma or any other breathing problems

Tell your doctor if you are pregnant or intend to become pregnant.

This medicine is not recommended for use during pregnancy. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you are using an IUD (intrauterine device) for birth control.

This medicine may decrease the effectiveness of IUDs.

Tell your doctor if you currently have an infection.

This medicine may hide some of the signs of an infection. This may make you think, mistakenly, that you are better, or 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 may interact with meloxicam. These include:

- any other medicines used to treat high blood pressure and some 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
- aspirin, salicylates or other NSAID medicines
- medicines used to thin your blood (such as warfarin, heparin and ticlopidine)
- lithium, a medicine used to treat some types of mood disorders
- 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
- pemetrexed, used to treat lung cancer
- medicines used to treat diabetes
- cholestyramine, a medicine used to treat high cholesterol levels in the blood
- corticosteroids (drugs usually used to treat inflammatory conditions, such as skin rash and asthma)
- some medicines used to treat irregular heartbeats (such as amiodarone and quinidine)
- some medicines used to treat fungal infections (such as fluconazole, ketoconazole, itraconazole)
- some sulfur antibiotics (such as sulfaphenazole and sulfamethoxazole)

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with meloxicam.

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

Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

For the treatment of osteoarthritis

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

However, your doctor will prescribe a dose suitable for your condition.

For the treatment of rheumatoid arthritis

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

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

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow meloxicam capsules whole, with a full glass of water.

When to take it

It is best to take meloxicam immediately after food to avoid the chance of an upset stomach.

Take this medicine at the same time each day, either morning or evening. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it for

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs of an overdose with meloxicam may include:

- nausea and/or vomiting
- headache
- drowsiness
- blurred vision
- dizziness
- fits or seizures

- low blood pressure
- difficulty in breathing
- impaired consciousness
- kidney failure.

While you are taking this medicine

Things you must do

Tell your doctor or pharmacist that you are taking this medicine if you are about to be started on any new 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.

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

Meloxicam 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.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take this medicine to treat any other condition unless your doctor tells you to.

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

Things to be careful of

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

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

Make sure you know how you react to meloxicam before you drive a car, 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 meloxicam, or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

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
- sore mouth or throat, discomfort when swallowing, runny or blocked nose, flu-like symptoms or cough
- 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
- 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 pain or tenderness in the stomach
- severe dizziness
- 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)

These may be serious side effects and you may need medical attention.

If you experience any of the following, stop taking meloxicam and contact your doctor immediately or go to the Accident and Emergency department 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 very serious side effects. You may need urgent medical attention or hospitalisation.

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

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Meloxicam looks like

They are available in the following strengths:

7.5 mg capsule: Light green/Light green, size '2' hard gelatin capsules filled with light yellow coloured granules.

15 mg capsule: Light green/Light yellow, size '2' hard gelatin capsules filled with light yellow coloured granules.

Ingredients

Each capsule contains either 7.5 mg or 15 mg of the active ingredient meloxicam.

In addition, each capsule also contains the following inactive ingredients:

- lactose monohydrate
- maize starch
- sodium citrate
- magnesium stearate
- brilliant blue FCF
- gelatin
- quinoline yellow (7.5 mg only)
- sunset yellow FCF
- titanium dioxide

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

They are available in blister packs of 10, 20, 30 and 100 capsules.

Not all strengths, pack types and/or pack sizes may be available.

Australian Registration Numbers

APO-Meloxicam 7.5 mg capsules (blister pack): AUST R 181191.

APO-Meloxicam 15 mg capsules (blister pack): AUST R
181194.

Sponsor

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