

Melox® Capsules

contains the active ingredient meloxicam

Consumer Medicine Information

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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 Melox. 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.

Use in children

Do not give meloxicam to children and adolescents under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant.** Meloxicam use is not recommended in pregnancy unless it is considered clinically essential.
- **You are breast-feeding.** Meloxicam may pass into human breast milk and may affect your baby.
- **You have had an allergic reaction to meloxicam, aspirin, any other NSAID medicines or any of the ingredients listed at the end of this leaflet. This includes rare inherited conditions of galactose intolerance** Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin. **If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- 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 currently have a peptic (stomach) ulcer

- 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 (eg. sulfaphenazole or sulfamethoxazole).
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines, including aspirin or other NSAID medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - high blood pressure or fluid retention
 - diabetes
 - high cholesterol
 - heartburn, indigestion, ulcers or other stomach problems
 - kidney or liver disease
 - asthma or any other breathing problems
3. You are using an IUD for birth control
4. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

5. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
6. You are planning to have surgery or an anaesthetic.
7. You are taking meloxicam together with any 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
8. You are taking or are planning to take any other medicines; this includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with meloxicam. These include:

- 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 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
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure
- medicines used to treat heart problems
- 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 fungal infections
- some sulfur antibiotics
- some medicines used to treat irregular heart beats
- some antihistamines (medicines used to prevent or relieve the symptoms of allergy, such as hay fever or insect stings).

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.

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

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.

How to take it

Swallow meloxicam capsules whole, with fluid.

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. 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.

Do not stop taking it unless your doctor tells you to - even if you feel better.

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 (e.g. within 2-3 hours), 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 that you are taking this medicine if:

- **you are about to be started on any new medicine**
- **you become pregnant**
- **you are breastfeeding or are planning to breastfeed**
- **you are about to have any blood tests**
- **you are going to have surgery, including dental surgery or are going into hospital.**

Meloxicam can slow down blood clotting.

- **you get an infection while using meloxicam**
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.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to

- Stop taking your medicine, or change the dosage, without first 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 if you

Possible side effects

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

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.

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
- constipation, diarrhoea or wind
- dizziness or light-headedness
- skin rash or itching
- 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 in the ear).

These are the more common side effects, mostly they are 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)
- 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
- 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)
- irritation of your mucous membranes (eg. lips, mouth, eyes or genitals).

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

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

- vomiting of blood or material that looks like coffee grounds
- bleeding from your back passage (rectum), black sticky motions (stools) or bloody diarrhoea
- weakness in one part or side of your body, slurred speech, blurred vision or visual disturbances
- sudden signs of allergy such as shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

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

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° Celsius.

Do not store your medicine in direct sunlight.

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 Melox 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

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

They are available in blister packs of 30 capsules.

Australian Registration Numbers

- Melox 7.5 mg capsules (blister pack):
AUST R 181206.
- Melox 15 mg capsules (blister pack):
AUST R 181207.

Sponsor

Spirit Pharmaceuticals Pty Ltd
117 Harrington St
The Rocks NSW 2000

Distributor

Ascent Pharma Pty Ltd
South Melbourne VIC 3205



www.ascentpharma.com.au

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