

# Melox® Capsules

contains the active ingredient meloxicam

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about MELOX.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking MELOX against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine. You may need to read it again.

### What MELOX is used for

MELOX is used to treat the symptoms of:

- osteoarthritis
- rheumatoid arthritis.

Both of these diseases mainly affect the joints causing pain and swelling.

Although MELOX can relieve symptoms such as pain and inflammation, it will not cure your condition.

MELOX 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

### Before you take MELOX

#### *When you must not take it*

##### **Do not take MELOX if you are allergic to:**

- any medicine containing meloxicam
- any of the ingredients listed at the end of this leaflet
- aspirin or 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
- rash, itching or hives on the skin.

##### **Do not take MELOX if you:**

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

- have or have had inflammation of the lining of the stomach or bowel (e.g. Crohn's Disease or Ulcerative Colitis)
- have 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 breast-feed if you are taking this medicine.**

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

##### **Do not give MELOX to children or adolescents under 18 years of age.**

Safety and effectiveness in children or adolescents younger than 18 years have not been established.

##### **Do not take MELOX if the expiry date (Exp.) printed on the pack has passed.**

##### **Do not take MELOX if the packaging shows signs of tampering or the capsules do not look quite right.**

**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 including aspirin and other NSAIDs
- any other substances, such as foods, preservatives or dyes.

##### **Tell your doctor 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
- asthma or any other breathing problems.

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

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you currently have an infection.**

MELOX 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 MELOX.**

**Taking other medicines**

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

Some medicines may be affected by MELOX, or may affect how well it works. These include:

- aspirin, salicylates or other NSAID medicines
- medicines used to thin your blood (such as warfarin, heparin and ticlopidine)
- medicines used to treat high blood pressure and other heart problems (e.g. 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 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 rash and asthma)
- some medicines used to treat infections (e.g. erythromycin, sulfur antibiotics, ketoconazole, itraconazole)
- some medicines used to treat irregular heart beats (eg amiodarone and quinidine)
- pemetrexed, a medicine used in the treatment of certain lung cancers.

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

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

## How to take MELOX

**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 MELOX 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 MELOX 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 MELOX 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 MELOX**

**Swallow the tablets with a glass of water.**

**When to take MELOX**

**Try to take MELOX 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.

**It is best to take MELOX with or straight after food.**

This may help the possibility of stomach upset.

**If you forget to take MELOX**

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

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your capsules as you would normally.**

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

**If you are not sure what to do, ask your doctor or pharmacist.**

#### *How long to take MELOX for*

**Continue taking MELOX for as long as your doctor tells you to.**

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

#### *If you take too much MELOX (overdose)*

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

You may need urgent medical attention.

Signs of an overdose with MELOX 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.

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## **While you are taking MELOX**

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#### *Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking MELOX.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking MELOX.**

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

**If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking MELOX.**

MELOX can slow down blood clotting.

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

MELOX 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 use MELOX to treat any other conditions unless your doctor tells you to.**

**Do not give MELOX 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 MELOX affects you.**

MELOX 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.

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## **Side effects**

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

Like all other medicines, MELOX may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

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

**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 or 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, 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)
- 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 happen, 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
- 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.

**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.

## After using MELOX

### Storage

**Keep MELOX 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.

**Keep your capsules in the pack until it is time to take them.**

If you take the capsules out of their packaging they may not keep well.

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

**Do not store MELOX or any other medicine in the bathroom or near a sink.**

**Do not leave MELOX in the car or on window sills.**

Heat and dampness can destroy some medicines.

*Disposal*

**If your doctor tells you to stop taking MELOX, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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.

*Supplier*

**Actavis Pty Ltd**  
117 Harrington St  
The Rocks NSW 2000  
Australia

*Date of preparation*

16 April 2015

## Product description

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.