

MELOXIBELL

Consumer Medicine Information

What is in this leaflet:

1. What MELOXIBELL is used for

2. Before you take MELOXIBELL

- When you must not take MELOXIBELL
- Before you start to take MELOXIBELL
- Taking other medicines
- Children

3. Taking MELOXIBELL

- How much to take
- How to take MELOXIBELL
- How long to take MELOXIBELL
- If you forget to take MELOXIBELL
- If you have taken too much MELOXIBELL

4. While you are taking MELOXIBELL

- Things you must do
- Things to be careful of

5. Side effects

6. After taking MELOXIBELL

- Storage
- Disposal

7. Product description

- What is MELOXIBELL
- Ingredients
- Manufacturer

MELOXIBELL is a registered trademark of Bellwether Pharma Ltd.

This leaflet answers some common questions about MELOXIBELL. It does not contain all available information, nor does it take the place of talking to your doctor or pharmacist. Keep this information. You may need to read it again later.

You should ask your doctor or pharmacist if you have any questions about MELOXIBELL or if you have any trouble before, during or after taking MELOXIBELL.

1. What MELOXIBELL is used for

MELOXIBELL is used to treat the symptoms of:

- osteoarthritis
- rheumatoid arthritis

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

MELOXIBELL 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 MELOXIBELL has been prescribed for you. Your doctor may have prescribed MELOXIBELL for another reason.

2. Before you take MELOXIBELL

2a) When you must not take MELOXIBELL

Do not take MELOXIBELL if you have an allergy to:

- the active ingredient, meloxicam, or any of the other ingredients in MELOXIBELL (all of these ingredients are listed in section 7b)
- aspirin or any other NSAID medicine

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 trouble breathing

If you are not sure if you have these allergies, you should raise those concerns with your doctor or pharmacist.

Do not take MELOXIBELL 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 are breastfeeding, or intend to breastfeed.
- The active ingredient in MELOXIBELL may pass into breast milk and may affect your baby.
- 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).

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

You should not use MELOXIBELL if the packaging is torn or shows signs of tampering.

You should not use MELOXIBELL after the EXPIRY DATE on the packaging has passed.

2b) Before you start to take MELOXIBELL

You must tell your doctor or pharmacist if:

- you have any allergies to any other medicines, including aspirin or other NSAID medicines.
- 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 pregnant or intend to become pregnant

If it is necessary for you to take MELOXIBELL, your doctor will discuss the risks and benefits of taking it during pregnancy.

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

2c) Taking other medicines

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

There may be interference between MELOXIBELL and some medicines. 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 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)

These medicines may be affected by MELOXIBELL or may affect how well MELOXIBELL works. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MELOXIBELL.

2d) Children

MELOXIBELL is not recommended for use in children and adolescents under 18 years of age.

3. Taking MELOXIBELL

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

3a) How much to take

For the treatment of osteoarthritis
The usual dose of MELOXIBELL 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 MELOXIBELL 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 MELOXIBELL 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.

3b) How to take MELOXIBELL

Swallow the tablets with fluid.

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

Try to take MELOXIBELL at the same time each day, either morning or evening.

3c) How long to take MELOXIBELL

Keep taking MELOXIBELL every day until your doctor tells you to stop. MELOXIBELL will not cure your condition but it should help control pain, swelling and stiffness.

3d) If you forget to take MELOXIBELL

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 try to make up for missed doses by taking more than one dose at a time.

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

3e) If you have taken too much MELOXIBELL

Seek urgent medical advice if you think that you or anyone else may have taken more than the recommended dose of MELOXIBELL.

Advice can be provided by a doctor, pharmacist or Poisons Information Centre (telephone 13 11 26).

Signs of an overdose with MELOXIBELL may include:

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

4. While you are taking MELOXIBELL

4a) Things you must do

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

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

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking MELOXIBELL. MELOXIBELL can slow down blood clotting.

If you get an infection while using MELOXIBELL, tell your doctor. MELOXIBELL may hide some of the signs of an infection (eg. pain, fever, redness and swelling). You may think, mistakenly, that you are better or that the infection is not serious.

4b) Things to be careful of

Be careful driving or operating machinery until you know how MELOXIBELL affects you. As with other NSAID medicines, MELOXIBELL may cause dizziness, drowsiness or blurred vision in some people.

Make sure you know how you react to MELOXIBELL before you drive a car, operate machinery, or do anything else that could be dangerous if you are not alert.

5. Side effects

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.

Check with your doctor as soon as possible if you have any problems while taking MELOXIBELL, 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, cramps or pain
- headache
- sore throat or discomfort when swallowing
- 'flu'-like symptoms, including coughing
- constipation, diarrhoea or wind

- dizziness or light-headedness, falls or other accidents around the home or work
- skin rash or itching
- back pain, muscle spasms or pain, painful or swollen joints
- clicking sound when joints move
- trouble sleeping
- laryngitis, a condition causing hoarseness or loss of voice
- 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)

These side effects are usually mild.

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

- infections in your lungs, throat or nose
- sinusitis, a condition causing a feeling of tension or fullness of the nose, cheeks and behind your eyes
- blurred vision
- infections in your urinary tract e.g. the need to pass urine more frequently than normal, any change in the amount or colour of your urine (red or brown) or painful urination
- 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 any of the following happen, STOP taking MELOXIBELL 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
- weakness in one part or side of your body, slurred speech 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 MELOXIBELL 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

6. After taking MELOXIBELL

6a) 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 MELOXIBELL in a cool dry place where the temperature stays below 25°C.

MELOXIBELL should not be stored in direct sunlight or heat.

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.

6b) Disposal

Your pharmacist should be able to safely dispose of any unused MELOXIBELL

7. Product Description

7a) What is MELOXIBELL

MELOXIBELL is the brand name of your medicine. It is available as

tablets. MELOXIBELL tablets come in two strengths:

MELOXIBELL 7.5 mg tablets are pale-yellow, circular, flat bevelled tablets with a central break-line on one side and plain on the other side.

Available in blister packs of 30 tablets.
AUST R 127413.

MELOXIBELL 15 mg tablets are pale-yellow, circular, flat bevelled tablets with a central break-line on one side and plain on the other side.

Available blister packs of 30 tablets.
AUST R 127414.

MELOXIBELL is available only with a doctor's prescription.

7b) Ingredients

The active ingredient in MELOXIBELL is meloxicam:

each MELOXIBELL 7.5 mg tablet contains 7.5 mg of meloxicam
each MELOXIBELL 15 mg tablet contains 15 mg of meloxicam

The tablets also contains microcrystalline cellulose, pregelatinised maize starch, lactose, starch- maize, sodium citrate, silica-colloidal anhydrous and magnesium stearate.

MELOXIBELL does not contain gluten or sucrose.

7c) Manufacturer

MELOXIBELL is supplied in Australia by:
Bellwether Pharma Ltd
Suite 1, 1175 Toorak Road
Camberwell, VIC 3124

This leaflet was prepared on:
9 January 2008.