

MELOXIBELL (meloxicam) uncoated tablet

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Meloxicam?

Meloxicam tablets contains the active ingredient meloxicam. Meloxicam is used to treat the symptoms of osteoarthritis and rheumatoid arthritis. For more information, see Section [1. Why am I using Meloxicam?](#) in the full CMI.

2. What should I know before I use Meloxicam?

Do not use Meloxicam if you have ever had an allergic reaction to meloxicam or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Meloxicam?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Meloxicam and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Meloxicam?

Follow the instructions provided by your doctor and pharmacist

- For **osteoarthritis**, the usual dose of Meloxicam is 7.5 mg once daily.
- For **rheumatoid arthritis**, the usual dose of Meloxicam is 15 mg once daily.

Swallow Meloxicam whole with a full glass of water with or immediately after food. More instructions can be found in Section [4. How do I use Meloxicam?](#) in the full CMI.

5. What should I know while using Meloxicam?

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| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist that you visit that you are taking Meloxicam.• If you are going to have surgery, tell the nurse, surgeon, or anaesthetist that you are taking Meloxicam as it can slow down blood clotting. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop taking Meloxicam or lower the dosage without checking with your doctor. |
| Driving or using machines | <ul style="list-style-type: none">• 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 |
| Looking after your medicine | <ul style="list-style-type: none">• Keep Meloxicam in a cool dry place where the temperature stays below 25°C.• Keep it where children cannot reach it. |

For more information, see Section [5. What should I know while using Meloxicam?](#) in the full CMI.

6. Are there any side effects?

Common side effects: aching muscles, allergic reactions, back pain, being sick, blood in the urine, burping, chest tightness, constipation, cough, cramps, dehydration, dizziness, drowsiness, excessive sweating, fatigue, feeling sick, fluid retention, flu-like symptoms, headache, heartburn, increased appetite, increased blood pressure, itching or flaking skin, joint pain, loose stools, muscle spasms/ tenderness/ weakness, pain, passing wind, reflux, runny or blocked nose, shortness of breath, sore mouth/throat, stomach upset, trouble sleeping, upper respiratory tract infections.

Serious side effects: asthma, blurred vision, heartbeat irregularities, infection, photosensitivity, rash, severe skin reactions, sharp chest pain, swelling of skin/mucous membranes/stomach/intestines/liver, ulcers, urine changes. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Meloxicam

Active ingredient(s): *meloxicam*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Meloxicam. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Meloxicam.**

Where to find information in this leaflet:

- [1. Why am I using Meloxicam?](#)
- [2. What should I know before I use Meloxicam?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Meloxicam?](#)
- [5. What should I know while using Meloxicam?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Meloxicam?

Meloxicam contains the active ingredient meloxicam.

Meloxicam belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain, swelling, and redness.

Meloxicam is used to treat the symptoms of:

- Osteoarthritis (OA)** is a chronic disorder that causes damage to the cartilage and surrounding tissues and is characterized by pain, stiffness, and loss of function.
- Rheumatoid arthritis (RA)** is an inflammatory arthritis in which joints, usually including those of the hands and feet, are inflamed, resulting in swelling, pain, and often destruction of joints.

Both diseases mainly affect the joints causing pain and swelling.

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

2. What should I know before I use Meloxicam?

Warnings

Do not use Meloxicam if you are allergic to:

- meloxicam, or any of the ingredients listed at the end of this leaflet. Always check the ingredients in section 7 to make sure that you can take this medicine.
- Aspirin or any other non steroidal anti inflammatory drugs (NSAIDs).

Do not take Meloxicam if you:

- Are under 18 years of age

- Are pregnant or think you may be pregnant (see Pregnancy and Breastfeeding)
- Are breastfeeding (see Pregnancy and Breastfeeding)
- Are going to have or have just had heart bypass surgery
- Have galactose intolerance (a rare genetic condition)
- Have a hole in or experience bleeding from the stomach, gut or any other bleeding
- Have uncontrolled heart failure
- Have severe liver problems
- Have severe, non-dialysis kidney disease
- Have had a stroke due to a bleed in the brain
- Have a stomach ulcer
- Have or have had inflammation of the stomach lining
- Have an inflammatory bowel disease such as Crohn's disease or ulcerative colitis now or in the past
- Are taking any of these medicines:
 - fluconazole (a medicine used to treat fungal infections) or
 - certain sulfur antibiotics (e.g. sulfamethoxazole)
 - methotrexate (a medicine used to treat diseases of the immune system and some cancers).
- Had any of the following reactions after taking aspirin or an NSAID:
 - asthma
 - nasal polyps (painless growths inside the nose or sinuses)
 - swelling of the face, lips, mouth, tongue or throat (which may cause difficulty in swallowing or breathing)
 - hives or an itchy rash.

Tell your doctor if you have:

- any allergies to other medicines, foods, preservatives, or colours
- a current infection
- advanced or chronic kidney disease
- any problems with your
 - heart or blood vessels
 - liver
 - blood pressure
- fluid retention
- diabetes
- high cholesterol
- any clotting or bleeding disorder
- asthma.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Speak to your doctor if you intend to become pregnant or breastfeed.

Tell your doctor immediately if you become pregnant while taking Meloxicam.

Birth control

Tell your doctor if you are using an intrauterine device (IUD) to prevent pregnancy. NSAID medicines, like Meloxicib, may decrease the effectiveness of the birth control device.

Children and adolescents

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Meloxicib and affect how it works. These include:

- other non-steroidal anti-inflammatory drugs (NSAIDs): aspirin, celecoxib, diclofenac, etoricoxib, ibuprofen, indometacin, ketoprofen, mefenamic acid, naproxen, piroxicam, rofecoxib, salicylates, or sulindac.
- warfarin or heparin, medicines used to thin the blood
- furosemide, other diuretics or medicines used to treat high blood pressure
- Amiodarone or quinidine, two medicines used to treat fast, slow or irregular heart beats
- Ciclosporin, a medicine used to treat inflammatory conditions suppress the immune system
- Ketoconazole and itraconazole, medicines used to treat fungal infections
- Erythromycin, a commonly used broad-spectrum antibiotic
- Lithium, a tablet used to treat mood disorders
- Cortisone, dexamethasone, prednisolone, prednisone, or any other steroid medicine used to treat inflammatory conditions (e.g. skin rashes or asthma)
- Pemetrexed, a medicine injected into a vein that is used to treat some lung cancers
- Sulfonylureas, oral medicines used to treat diabetes
- citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, or sertraline, medicines used to treat depression and anxiety (called SSRIs).

Medicines that may reduce the effect of Meloxicib include:

- Cholestyramine, a medicine used for lowering blood Fats (cholesterol).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Meloxicib

4. How do I use Meloxicib?

How much to take

The dose depends on your condition and any medicines that you are taking.

Follow the instructions provided by your doctor and pharmacist and take Meloxicib until your doctor tells you to stop.

Osteoarthritis (OA)

The usual starting dose for osteoarthritis is 7.5 mg, taken as a single dose each day. Depending on your response, your doctor may increase the single daily dose to 15 mg.

Rheumatoid arthritis (RA)

The usual dose for rheumatoid arthritis is 15 mg taken as a single dose each day. If needed, your doctor may reduce the single daily dose to 7.5 mg.

Ask your doctor for more information if you have been advised to take a different dose.

Patients with kidney problems undergoing dialysis should not take more than 7.5 mg each day.

Do not exceed the maximum recommended daily dose of 15 mg.

How to take Meloxicib

Swallow Meloxicib whole with a full glass of water with or immediately after food. This may help reduce the risk of getting an upset stomach.

When to take Meloxicib

Take Meloxicib once a day, at about the same time each day. Taking it at the same time each day will help you remember when to take it.

If you forget to take Meloxicib

If you miss taking your dose at the usual time, and it is 2-3 hours before your next dose, skip the dose you missed and take your 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 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.

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

If you have taken too much Meloxicib

If you think that you have taken too much Meloxicib, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

The symptoms of an overdose may include:

- nausea and/or vomiting

- headache
- drowsiness and/or dizziness
- blurred vision
- fits or seizures
- fainting, feeling weak, light-headed, tired, confused and having blurred vision (signs of low blood pressure)
- difficulty in breathing
- being unaware of what happens to you or around you
- changes in amount of urine, fluid retention, confusion, and/or nausea.

5. What should I know while using Meloxicibell?

Things you should do

If you are going to have surgery, tell the nurse, surgeon, or anesthetists that you are taking Meloxicibell. Meloxicibell can slow down blood clotting and put you at risk of bleeding.

Keep your medical appointments so that your progress can be monitored.

Your doctor may want to perform tests now and then to detect any side effects, such as anaemia.

Tell any healthcare professionals who treat you that you are taking this medicine.

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

Talk to your doctor or pharmacist if you do not feel any better after several days of taking Meloxicibell

Things you should not do

Do not stop taking your medicine or lower the dosage Without speaking to your doctor first.

Things to be careful of

Tell your doctor if you get an infection while using Meloxicibell. Meloxicibell may hide some of the signs of an infection, such as pain, fever, redness and swelling. You may think, mistakenly, that you have improved or that the infection is not serious.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Meloxicibell affects you.

Meloxicibell may cause dizziness 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.

Looking after your medicine

Store Meloxicibell in a cool dry place where the temperature stays below 25°C.

Store Meloxicibell away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

Return Meloxicibell to your pharmacist for safe disposal if:

- your doctor tells you to stop taking it or
- the pack has expired or
- the packaging is torn/shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>General problems:</p> <ul style="list-style-type: none"> • Flu-like symptoms: runny or blocked nose, cough, sore mouth or throat, discomfort when swallowing • fatigue • fluid retention in lower body • swelling of hands, ankles or feet • allergic reaction. <p>Gut and digestion:</p> <ul style="list-style-type: none"> • indigestion (stomach upset) including heartburn/reflux, feeling sick (nausea), vomiting, burping or passing more wind than usual, cramps, pain, constipation, loose stools (diarrhoea). <p>Nervous system:</p> <ul style="list-style-type: none"> • headache • dizziness • spinning sensation • trouble sleeping • drowsiness. <p>Skin:</p> <ul style="list-style-type: none"> • itching or flaking • excessive sweating that's not related to heat or exercise • irritation of the moist internal linings of the body such as the mucous membranes (e.g. lips, mouth, throat, nasal passages, eyelids, intestines or genitals). <p>Breathing:</p> <ul style="list-style-type: none"> • cough • shortness of breath, chest tightness. | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

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| <p>Nutrition:</p> <ul style="list-style-type: none"> • dehydration • increased appetite. <p>Muscle and bone:</p> <ul style="list-style-type: none"> • back pain • pain or swelling in or near a joint • muscle spasms • aching muscles, muscle tenderness or weakness, not caused by exercise • pain in extremity. <p>Infections:</p> <ul style="list-style-type: none"> • runny or stuffy nose, sneezing, or swelling of the lining of the nose • swelling of the air-filled spaces in your forehead, cheeks or nasal passages. <p>Urine:</p> <ul style="list-style-type: none"> • blood in the urine. <p>Blood:</p> <ul style="list-style-type: none"> • increased blood pressure (BP) over several days (if self-checked at home with a suitable BP machine). | |
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| <ul style="list-style-type: none"> • swollen ankles or legs (oedema of the lower limbs). <p>Severe allergic reaction:</p> <ul style="list-style-type: none"> • 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. <p>Severe skin and soft tissue reactions:</p> <ul style="list-style-type: none"> • sudden unexplained bruising or blood spots under the skin that were not caused by an injury • itching, blistering or peeling of the skin, which can be potentially life-threatening • rashes which may be caused by sunlight, can blister, and may take on the appearance of a severe burn • swelling of skin or mucosa, such as swelling around the eyes, face and lips, mouth or throat, possibly making breathing difficult. | |
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Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>Gut and bowel:</p> <ul style="list-style-type: none"> • bleeding from the back passage, black sticky stools or bloody diarrhoea • severe pain or tenderness in the stomach • vomiting of blood or material that looks like coffee grounds. <p>Liver:</p> <ul style="list-style-type: none"> • yellowing of the skin or the whites of the eyes • pain in the abdomen • loss of appetite. <p>Kidney and bladder:</p> <ul style="list-style-type: none"> • any pain or difficulty when urinating • any change in the amount or colour of urine. <p>Eyes:</p> <ul style="list-style-type: none"> • blurred vision or difficulty seeing. <p>Lungs:</p> <ul style="list-style-type: none"> • sharp chest pain, usually worse when you inhale or cough. <p>Heart:</p> <ul style="list-style-type: none"> • fast or irregular heartbeat • chest pain | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Very serious side effects

| Very Serious side effects | What to do |
|--|--|
| <p>Signs of a stroke</p> <ul style="list-style-type: none"> • weakness or numbness or paralysis of the face, arm or leg on either or both sides of the body • slurred speech • difficulty speaking or understanding • loss of vision, sudden blurring or decreased vision in one or both eyes • Headache, usually severe and fast onset or unexplained change in the pattern of headaches. | <p>Call an ambulance (dial 000) at once if you experience these side effects.</p> |

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Meloxibell contains

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|-------------------------------------|---|
| Active (main ingredient) | meloxicam |
| Other (inactive ingredients) | <ul style="list-style-type: none">• colloidal anhydrous silica;• lactose monohydrate;• magnesium stearate;• maize starch;• microcrystalline cellulose;• pregelatinised maize starch;• sodium citrate dihydrate. |

Do not take this medicine if you are allergic to any of these ingredients.

Meloxibell does not contain gluten or sucrose.

What Meloxibell looks like

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. 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. AUST R 127414

Both strengths are available in blister packs of 30 tablets.

Who distributes Meloxibell

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