

MELOXICAM SANDOZ

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 SANDOZ?

MELOXICAM SANDOZ contains the active ingredient meloxicam. MELOXICAM SANDOZ is used to treat the symptoms of osteoarthritis and rheumatoid arthritis.

For more information, see Section [1. Why am I using MELOXICAM SANDOZ?](#) in the full CMI.

2. What should I know before I use MELOXICAM SANDOZ?

Do not use 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.

Do not use at all during the last three months of pregnancy.

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

3. What if I am taking other medicines?

Some medicines may interfere with MELOXICAM SANDOZ 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 SANDOZ?

- For the treatment of osteoarthritis: The usual dose of MELOXICAM SANDOZ is 7.5 mg, taken as a single dose each day.
- For the treatment of rheumatoid arthritis: The usual dose of MELOXICAM SANDOZ is 15 mg taken as a single dose each day.

Swallow the tablets whole with a full glass of water.

More instructions can be found in Section [4. How do I use MELOXICAM SANDOZ?](#) in the full CMI.

5. What should I know while using MELOXICAM SANDOZ?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist when you visit that you are using MELOXICAM SANDOZ.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking MELOXICAM SANDOZ. MELOXICAM SANDOZ can slow down blood clotting.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine 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 SANDOZ 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 your tablets in blister pack and 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 SANDOZ?](#) in the full CMI.

6. Are there any side effects?

Serious side effects includes blurred vision, difficulty experienced when urinating, collapse or fainting, shortness of breath or tiredness, fast or irregular heartbeat, chest pain, severe dizziness, severe pain or tenderness in the stomach, yellowing of the skin and eyes (known as jaundice), swelling of your ankles, legs or other parts of your body, signs of anaemia, irritation of your mucous membranes (eg. lips, mouth, eyes or genitals), vomiting of blood or material that looks like coffee grounds, bleeding from your back passage (rectum), black sticky motions (stools) or bloody diarrhoea, asthma, sudden or severe itching, skin rash or hives, weakness in one part or side of your body, slurred speech, , decrease in amniotic fluid in pregnancy, abnormal renal function specially in neonates. 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 SANDOZ

Active ingredient: *Meloxicam*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using MELOXICAM SANDOZ?

MELOXICAM SANDOZ contains the active ingredient meloxicam. MELOXICAM SANDOZ belongs to a family of medicines called Non-Steroidal Anti-inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

MELOXICAM SANDOZ is used to treat the symptoms of:

- osteoarthritis
- rheumatoid arthritis

Both diseases mainly affect the joints causing pain and swelling.

Although MELOXICAM SANDOZ can relieve symptoms of 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 it for another reason.

2. What should I know before I use MELOXICAM SANDOZ?

Warnings

Do not use MELOXICAM SANDOZ if:

- you are allergic to meloxicam, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have allergy to aspirin or any 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
- you are a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.
- 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 had a stroke resulting from a bleed in the brain or have a bleeding disorder
- you have a peptic (stomach) ulcer
- you have or have had inflammation of the lining of the stomach or bowel (e.g. Crohn's Disease or Ulcerative Colitis)
- you have severe liver or kidney problems
- you are currently taking the following medicines: fluconazole (used to treat fungal infections) or certain sulfur antibiotics (eg. sulfamethoxazole).
- you are in the third trimester of pregnancy (see Pregnancy and breastfeeding).

Check with your doctor if you:

- have high blood pressure or fluid retention
 - have diabetes
 - have high cholesterol
 - have heartburn, indigestion, ulcers or other stomach problems
 - have kidney or liver disease
 - have asthma or any other breathing problems.
 - currently have an infection.
- MELOXICAM SANDOZ 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.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take at all during the last three months (third trimester) of pregnancy. It may affect your developing baby if you take it during pregnancy.

Please let your prescriber know if you have been exposed during pregnancy

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

NSAID medicines, like MELOXICAM SANDOZ, may decrease the effectiveness of IUDs.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breast-feed if you are taking this medicine.

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

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 MELOXICAM SANDOZ and affect how it works. e.g.

- aspirin, salicylates or other NSAIDs
- medicines used to thin your blood (e.g. 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
- ciclosporin, 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
- colestyramine, a medicine used to treat high cholesterol levels in the blood
- corticosteroids, medicines usually used to treat inflammatory conditions, such as skin rashes and asthma
- some medicines used to treat infections (e.g. erythromycin, sulfur antibiotics, ketoconazole, itraconazole)
- some medicines used to treat irregular heart beats (e.g. amiodarone and quinidine).
- pemetrexed, a medicine used in the treatment of certain lung cancers.

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

4. How do I use MELOXICAM SANDOZ?

How much to take / use

- Follow the instructions provided and use MELOXICAM SANDOZ until your doctor tells you to stop.
- For the treatment of osteoarthritis
 - The usual dose of MELOXICAM SANDOZ 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 MELOXICAM SANDOZ 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 SANDOZ 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.

When to take MELOXICAM SANDOZ

- Swallow the tablets whole with a full glass of water.
- Take your medicine 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
- Take your medicine with or straight after food.
- This may help reduce the possibility of stomach upset.
- Continue taking your medicine for as long as your doctor tells you.
- 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 forget to use MELOXICAM SANDOZ

MELOXICAM SANDOZ should be used regularly at the same time each day.

If you miss your dose at the usual time and if it is almost time for 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 use too much MELOXICAM SANDOZ

If you think that you have used too much MELOXICAM SANDOZ, 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.

You may need urgent medical attention.

Symptoms of an overdose 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

5. What should I know while using MELOXICAM SANDOZ?

Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

Call your doctor straight away if you:

- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking MELOXICAM SANDOZ. MELOXICAM SANDOZ can slow down blood clotting.
- If you get an infection while using MELOXICAM SANDOZ, tell your doctor. MELOXICAM SANDOZ 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.

Remind any doctor, dentist or pharmacist when you visit that you are using MELOXICAM SANDOZ.

Things you should not do

- Do not take MELOXICAM SANDOZ to treat any other complaints unless your doctor tell you to.
- Do not give your medicine 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.

Driving or using machines

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

MELOXICAM SANDOZ 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

- Keep your tablets in their pack until it is time to take them.
- If you take them out of the pack they may not keep well.
- Keep your tablets in blister pack and in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place 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.
- Heat and dampness can destroy some medicines
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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
<ul style="list-style-type: none">• 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	Speak to your doctor if you have any of these less serious side effects and they worry you.

and may take on the appearance of a severe burn or itching <ul style="list-style-type: none"> • increase in blood pressure • tinnitus (ringing in the ear) 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 (eg. lips, mouth, eyes or genitals). • 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. • complications during pregnancy • fever, swelling around the face, feet, ankles, decreased or no urine output which may be indicative of kidney complications in a newborn • swollen lymph glands 	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.

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 MELOXICAM SANDOZ contains

Active ingredient (main ingredient)	Meloxicam
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Microcrystalline cellulose, • Pregelatinised maize starch, • Lactose monohydrate, • Maize starch, • Sodium citrate, • Hydrophobic colloidal silica anhydrous • Magnesium stearate.

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

What MELOXICAM SANDOZ looks like

MELOXICAM SANDOZ tablet comes in two strengths:

MELOXICAM SANDOZ 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 288943).

MELOXICAM SANDOZ 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 288944).

Who distributes MELOXICAM SANDOZ

Sandoz Pty Ltd

54 Waterloo Road Macquarie

Park NSW 2113 AUSTRALIA:

Email id: drugsafety@cipla.com

Phone no: 1 800 569 074

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