

# MELOXICAM SANDOZ

## Meloxicam Sandoz 7.5; Meloxicam Sandoz 15

*meloxicam*

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### Consumer Medicine Information

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#### What is in this leaflet:

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This leaflet answers some common questions about MELOXICAM SANDOZ. 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 MELOXICAM SANDOZ or if you have any trouble before, during or after taking MELOXICAM SANDOZ

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#### What MELOXICAM SANDOZ is used for

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MELOXICAM SANDOZ is used to treat the symptoms of:

- osteoarthritis
- rheumatoid arthritis

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

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

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#### Before you take MELOXICAM SANDOZ

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##### *When you must not take MELOXICAM SANDOZ*

Do not take MELOXICAM SANDOZ if you have an allergy to:

- the active ingredient, meloxicam, or any of the other ingredients in MELOXICAM SANDOZ (all of these ingredients are listed at the end of this leaflet)
- 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 MELOXICAM SANDOZ 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 MELOXICAM SANDOZ may pass into breast milk and may affect your baby
- you currently have a peptic (stomach) ulcer
- have a galactose intolerance
- 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 MELOXICAM SANDOZ to children and adolescents under 18 years of age.**

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

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

##### *Before you start to take MELOXICAM SANDOZ*

You must tell your doctor or pharmacist if:

1. you have any allergies to any other medicines, including aspirin or other NSAID medicines.

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 pregnant or intend to become pregnant

If it is necessary for you to take MELOXICAM SANDOZ, 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 MELOXICAM SANDOZ.

### *Taking other medicines*

Before taking MELOXICAM SANDOZ, 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 MELOXICAM SANDOZ 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 (e.g. erythromycin, ketoconazole, itraconazole)
- some sulfur antibiotics
- some medicines used to treat irregular heart beats (e.g. amiodarone and quinidine)
- some antihistamines (medicines used to prevent or relieve the symptoms of allergy, such as hay fever or insect stings)
- pemetrexed, a medicine used in the treatment of certain lung cancers

These medicines may be affected by MELOXICAM SANDOZ or may affect how well MELOXICAM SANDOZ works.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MELOXICAM SANDOZ.

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

### *Taking MELOXICAM SANDOZ*

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 MELOXICAM SANDOZ 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 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.

### *How to take MELOXICAM SANDOZ*

Swallow the tablets with fluid.

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

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

### *How long to take MELOXICAM SANDOZ*

Keep taking MELOXICAM SANDOZ every day until your doctor tells you to stop.

MELOXICAM SANDOZ will not cure your condition but it should help control pain, swelling and stiffness.

### *If you forget to take MELOXICAM SANDOZ*

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.

### *If you have taken too much MELOXICAM SANDOZ*

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

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

Signs of an overdose with MELOXICAM SANDOZ may include:

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

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## While you are taking MELOXICAM SANDOZ

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### *Things you must do*

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

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

If you are going to have surgery, including dental surgery, tell your

doctor or dentist 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.

### *Things to be careful of*

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

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

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## Side effects

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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 MELOXICAM SANDOZ, 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 hoarse-ness 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 MELOXICAM SANDOZ 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 MELOXICAM SANDOZ 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.

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## After taking MELOXICAM SANDOZ

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### 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 MELOXICAM SANDOZ in a cool dry place where the temperature stays below 25°C.

MELOXICAM SANDOZ 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.

### Disposal

Your pharmacist should be able to safely dispose of any unused MELOXICAM SANDOZ.

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## Product Description

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### What is MELOXICAM SANDOZ

MELOXICAM SANDOZ is the brand name of your medicine. It is available as tablets. MELOXICAM SANDOZ tablets come in two strengths:

MELOXICAM SANDOZ 7.5 is a pale yellow, circular, flat bevelled tablet with a central break-line on one side and plain on the other side.

Available in blister packs of 30 tablets.

Australian Registration Number:  
**AUST R 288943**

MELOXICAM SANDOZ 15 is a pale yellow, circular, flat bevelled tablet with a central break-line on one side and plain on the other side.

Available blister packs of 30 tablets. **AUST R 288944**

MELOXICAM SANDOZ is available only with a doctor's prescription.

### Ingredients

The active ingredient in MELOXICAM SANDOZ is meloxicam.

Each MELOXICAM SANDOZ 7.5 tablet contains 7.5 mg of meloxicam.

Each MELOXICAM SANDOZ 15 tablet contains 15 mg of meloxicam.

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

MELOXICAM SANDOZ does not contain gluten or sucrose.

### Distributor

MELOXICAM SANDOZ is distributed in Australia by:

Sandoz Pty Ltd  
54 Waterloo Road  
Macquarie Park NSW 2113  
AUSTRALIA

### Sponsor

Pharmacor Pty Ltd.  
Suite-501, 7 Oaks Ave.  
Dee Why, NSW 2099

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