

Metoprolol Sandoz®

Metoprolol tartrate tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Metoprolol Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT METOPROLOL SANDOZ IS USED FOR

This medicine is used to treat:

- high blood pressure (hypertension).
- heart attack (myocardial infarction).
- prevent severe chest pain (angina pectoris).
- migraine.

It contains the active ingredient metoprolol tartrate.

Metoprolol Sandoz belongs to a group of medicines called beta-blockers.

It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood

and oxygen and therefore reduces the amount of work the heart has to do. It also widens the blood vessels in the body, causing blood pressure to fall.

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.

There is no evidence that Metoprolol Sandoz is addictive.

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

There is not enough information to recommend the use of this medicine for children.

BEFORE YOU TAKE METOPROLOL SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- metoprolol tartrate, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines such as other 'beta-blockers'.

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 this medicine if you have or have had any of the following medical conditions:

- asthma, difficulty breathing or other lung problems, or have had them in the past
- a history of allergic problems, e.g. hay fever
- low blood pressure
- a very slow heart beat (less than 45-50 beats/minute)
- sudden and oppressive chest pain, sign of heart attack
- irregular heart beat
- heart failure, heart disorders or other heart conditions
- a severe blood vessel disorder causing poor circulation in the arms and legs
- severe drop in blood pressure, dizziness, fast heart beat, rapid and shallow breathing, cold clammy skin
- sudden loss of consciousness sometimes
- phaeochromocytoma (a rare tumour of the adrenal gland) which is not already being treated with other medicines
- swollen ankles and/or tiredness due to heart disease or certain other heart conditions.
- poor blood circulation in your limbs (for example, very cold, pale hands or feet, or pain in your leg muscles when you walk)
- an operation where an anaesthetic is used during treatment
- respiratory diseases such as asthma
- oculomucocutaneous syndrome (signs include severe

conjunctivitis and skin rash and ear infection).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

Do not give Metoprolol Sandoz to children.

The safety and effectiveness of Metoprolol Sandoz has not been established.

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, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies. Beta-blocker medicines can make allergic reaction worse.

Tell your doctor if you have or have had any of the following medical conditions:

- any other heart problems
- chest pain when you are at rest, or certain types of angina, such as Prinzmetal angina or variant angina
- diabetes
- kidney or liver problems
- an overactive thyroid gland

Tell your doctor if you are pregnant or plan to become pregnant.

Metoprolol Sandoz should not be used throughout pregnancy, especially during the first 3 months of pregnancy, unless clearly necessary. Metoprolol Sandoz may affect your baby, especially if you take it in the last few days before your baby is born. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or intend to breast-feed.

The active ingredient in Metoprolol Sandoz passes into breast milk and

there is a possibility that your baby could be affected.

If you have not told your doctor about any of the above, tell him/her before you start taking Metoprolol Sandoz.

Taking other medicines

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

Some medicines and Metoprolol Sandoz may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- calcium channel blockers or calcium antagonists, used to treat high blood pressure and angina, for example verapamil, diltiazem and nifedipine
- some medicines used to treat angina
- adrenaline or similar substances, which are often found in eye or nose drops, or in cough and cold medicines
- certain medicines used to treat abnormal or irregular heart beat, for example disopyramide and quinidine
- clonidine, used to treat high blood pressure
- insulin and tablets used to treat diabetes
- quanethidine, a medicine used to treat certain heart conditions
- monoamine-oxidase inhibitors (MAOIs), used to treat depression
- cimetidine, used to treat stomach ulcers or reflux
- certain medicines, including non-steroidal anti-inflammatory drugs such as COX-2 inhibitors, used to relieve pain, swelling and other symptoms of inflammation and arthritis
- warfarin, a medicine used to prevent blood clots

- certain anaesthetics used during surgery
- rifampicin, used to treat tuberculosis
- ritonavir, an antiviral medicine
- diphenhydramine, an antihistamine
- terbinafine, used to treat fungal infections
- SSRIs such as paroxetine, fluoxetine, bupropion and sertraline
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches
- dipyridamole, a medicine used to reduce the risk of blot clots
- other medicines that may cause a decrease in heart rate (e.g. fingolimod, a medicine used to treat multiple sclerosis)
- other medicines that may cause a decrease in blood pressure (e.g. aldesleukin, a medicine used to treat kidney cancer).

These medicines may be affected by Metoprolol Sandoz, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

HOW TO TAKE METOPROLOL SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Hypertension (high blood pressure)

The usual dosage is 50 mg to 100 mg either once or twice daily. Your doctor may start you on a low dose and increase it over a period of time.

Angina pectoris (chest pain)

The usual dosage is 50 mg to 100 mg two to three times daily.

Myocardial infarction (heart attack)

Your doctor may start you on 50 mg twice daily for two days and then continue with 100 mg twice daily.

Migraine

The usual dose is 100 mg to 150 mg each day, divided into two doses (morning and evening)

The daily dosage should not exceed 400 mg.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Metoprolol Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablet with a glass of fluid.

When to take Metoprolol Sandoz

Take your medicine at about the same time each day before or after food.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you need to break Metoprolol Sandoz, place it on a hard surface (e.g. table or benchtop), and snap it along the break line with two fingers.

How long to take Metoprolol Sandoz

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

This medicine helps to 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 take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Metoprolol Sandoz.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling sick and vomiting, bluish skin and nails, very low blood pressure, slow heart beat, difficulty breathing, fainting, convulsions (fits) or coma.

WHILE YOU ARE TAKING METOPROLOL SANDOZ

Things you must do

- If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor. Metoprolol Sandoz may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia). Metoprolol Sandoz may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicine, including insulin, may need to change.
- Tell your doctor immediately if you develop a severe allergic reaction to any food, medicine or insect sting while taking Metoprolol Sandoz.
- Make sure that you drink enough water during exercise and hot weather when you are taking Metoprolol Sandoz, especially if you sweat a lot. If you do not drink enough water while taking Metoprolol Sandoz, you may feel faint or light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.
- If you feel light-headed, get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.
- Elderly patients especially need to be monitored to stop their blood pressure falling too far.

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are taking Metoprolol Sandoz.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not take Metoprolol Sandoz to treat any other complaints unless your doctor tells 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.

Do not stop taking this medicine suddenly. By stopping suddenly, your angina may worsen or other heart complications may occur. Your doctor may want you to gradually reduce the amount of Metoprolol Sandoz you are taking before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Metoprolol Sandoz affects you.

This medicine may cause dizziness, headaches, and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light headedness may be worse.

Dress warmly during the cold weather.

You may feel colder, especially if you will be outside for a long time (for example when playing winter sports). Metoprolol Sandoz, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have circulation problems.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need urgent medical attention if you get some side effects.

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

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:

- tiredness, drowsiness, headache, weakness, or lack of energy
- aches and pains, painful joints
- nausea, vomiting
- muscle cramps and weakness
- stomach upset, diarrhoea or constipation, weight gain
- dry mouth, changes in taste sensation
- difficulty sleeping, nightmares
- depression or mood changes
- confusion, short-term memory loss, inability to concentrate
- increased sweating, runny or blocked nose
- numbness, tingling in the extremities
- hair loss.

These are mild side effects of the medicine.

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

- dizziness, light headedness (sometimes with fainting) especially on standing up, which may be due to low blood pressure
- skin reactions (e.g. rash, itching, worsening of psoriasis)
- irritated eyes (red, runny, itchy or dry), visual disturbances (e.g. blurred vision)
- numbness in the arms and legs
- buzzing and ringing in the ears, difficulty hearing
- tingling or "pins and needles"
- sunburn happening more quickly than usual
- abnormal thinking or hallucinations
- constant "flu-like" symptoms with tiredness or lack of energy
- sexual problems
- breathlessness, difficulty breathing when lying down.
- abnormal triglycerides or cholesterol values, or liver function tests
- sleepiness during the day or troubled sleep
- coldness, burning, numbness or pain in arms and legs
- pain behind the breastbone (different from angina)
- constant "flu-like" symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy)
- increased sweating
- hair thinning
- confusion or loss of memory
- unusual bleeding or bruising

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking Metoprolol Sandoz, and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- shortness of breath, sometimes with tiredness and reduced ability to exercise, and swelling of the feet or legs due to fluid build up
- chest pain, chest tightness, changes in heart rate or palpitations
- yellowing of the skin or eyes (jaundice), generally feeling unwell.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

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

Other side effects not listed above may also occur in some people.

AFTER TAKING METOPROLOL SANDOZ

Storage

Keep Metoprolol Sandoz in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C and away from direct sunlight.

Do not store Metoprolol Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

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.

This leaflet was revised in June 2020.

Australian Register Numbers

50 mg tablets: AUST R 62560

100 mg tablets: AUST R 62561

PRODUCT DESCRIPTION

What it looks like

Metoprolol Sandoz 50 mg: white, round tablets, scored on one side. Available in blisters of 100 tablets.

Metoprolol Sandoz 100 mg: white, round tablets, scored on one side. Available in blisters of 60 tablets.

Ingredients

Active ingredients:

- Metoprolol Sandoz 50 mg - 50 mg metoprolol tartrate
- Metoprolol Sandoz 100 mg - 100 mg metoprolol tartrate

Inactive ingredients:

- lactose
- maize starch
- microcrystalline cellulose
- magnesium stearate
- colloidal anhydrous silica
- hydroxypropylcellulose
- calcium hydrogen phosphate
- crospovidone.

Contains sugar as lactose.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

Novartis New Zealand Ltd
PO Box 99102
Newmarket
Auckland 1149
New Zealand
Tel: 0800 354 335