

METROL

metoprolol tartrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about METROL.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with your medicine. You may need to read it again.

What METROL is used for

It is used to:

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

METROL 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.

Your doctor may have prescribed the medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

METROL is available only with a doctor's prescription.

It is not addictive.

Before you take it

When you must not take it

Do not take METROL if you are allergic to medicines containing metoprolol tartrate or any other beta-blocker medicine or any of the ingredients listed at the end of this leaflet.

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

- sudden loss of consciousness sometimes
- 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

- swollen ankles and/or tiredness due to heart disease or certain other heart conditions
- a severe blood vessel disorder causing poor circulation in the arms and legs
- phaeochromocytoma (a rare tumour of the adrenal gland) which is not already being treated with other medicines
- 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
- poor blood circulation in your limbs (for example, very cold, pale hands or feet, or pain in your leg muscles when you walk)
- oculomucocutaneous syndrome (signs include severe conjunctivitis and skin rash and ear infection)

Do not take METROL if the expiry date (Exp.) printed on the pack has passed.

Do not take it if the packaging is torn or shows signs of tampering.

Do not give the medicine to children.

The safety and effectiveness of METROL in children has not been established.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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
- 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.

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

Tell your doctor if you are breastfeeding or wish to breastfeed.

The active ingredient in METROL passes into breast milk and there is a possibility that your baby could be affected.

Tell your doctor if you plan to have surgery.

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

Taking other medicines

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

Some medicines may be affected by METROL, or may affect how well it works. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- calcium channel blockers or calcium antagonists, used to treat high blood pressure or angina, for example verapamil, diltiazem and nifedipine and
- some medicines used to treat angina
- adrenaline or similar substances, which are often found in eye or nose drops, or in some cough and cold medicines
- certain medicines used to treat abnormal or irregular heart beat (arrhythmias), for example disopyramide and quinidine
- clonidine, used to treat high blood pressure
- insulin and tablets used to treat diabetes
- guanethidine, a medicine used to treat certain heart conditions
- certain anaesthetics used during surgery
- monoamine-oxidase inhibitor (MAOI) medicines, used to treat depression
- some other antidepressant medications including fluoxetine, paroxetine, sertraline or bupropion
- warfarin, a medicine used to prevent blood clots
- indomethacin, a medicine for arthritis, pain or inflammation
- cimetidine, a medicine for stomach ulcers
- 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
- some antibiotics such as rifampicin
- some antivirals such as ritonavir
- some antihistamines such as diphenhydramine
- some antifungals such as terbinafine
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches
- dipyridamole, a medicine used to reduce the risk of blood clots.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take METROL

How much to take

Hypertension (high blood pressure)

The usual dose is from 50 mg to 200 mg each day, either as a single dose or divided into two doses. Your doctor may start you on a low dose and increase it over a period of time.

Angina pectoris (chest pain)

The usual dose is from 100 mg to 300 mg each day, divided into two or three doses.

Myocardial infarction (heart attack)

Your doctor may start you on 50 mg twice daily for the initial two days of treatment. The usual dose is 200 mg each day, divided into two doses.

To prevent migraine

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

Follow all directions given to you by your doctor and 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 to take METROL

Swallow the tablet with a glass of fluid.

Take your tablets at about the same time each day.

The tablets can be taken before or after food.

If you need to break METROL, hold tablet with both hands and snap along break line.

If you forget to take it

If it is almost time for your next dose (within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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.

How long to take it for

Continue taking METROL until your doctor tells you to stop.

METROL helps control your condition, but does not cure it. Therefore you must take it every day.

Do not stop taking it suddenly.

The dose of this medicine needs to be reduced slowly over 7 to 14 days.

If you take too much METROL (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much METROL. 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 or vomiting, bluish skin and nails, very low blood pressure, dizziness or light-headedness, slow heart beat, difficulty breathing, fainting, convulsions (fits) or coma.

While you are taking it

Things you must do

Be sure to keep all of your doctor's appointments so that your progress can be checked.

This helps your doctor to give you the best treatment and to prevent unwanted side effects from happening.

If you become pregnant while taking METROL, tell your doctor.

Your doctor can discuss with you the risks and benefits of taking it while you are pregnant.

If you have an allergic reaction to a food, another medicine or an insect sting while you are taking METROL, tell your doctor immediately.

There is a chance that it could make the allergic reaction worse or harder to treat.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you start to take METROL. This is because your blood pressure is falling suddenly. If this problem doesn't go away, talk to your doctor.

To avoid symptoms of low blood pressure, here are some hints that may help:

- stand up slowly to help your body get used to the change in position and blood pressure
- if you feel dizzy, sit or lie down until you feel better
- if you feel faint, breathe deeply and bend forward with your head between your knees
- take extra care when exercising, driving or standing for long periods, especially in hot weather. Drink plenty of fluids, especially if you sweat a lot.

If you are being treated for diabetes, make sure you check your blood sugar regularly and report any problems to your doctor.

METROL may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia). METROL may increase the time your body takes to recover from low blood sugar. The dose of your diabetes medicines, including insulin, may need to be changed.

If you plan to have surgery and will need an anaesthetic, tell your doctor or dentist that you are taking it.

This will help your doctor to prevent unwanted side effects such as a sudden drop in blood pressure.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking METROL.

Tell any other doctor, dentist or pharmacist who treats you that you are taking METROL.

Things you must not do

Do not stop taking METROL, or lower the dose, without checking with your doctor.

Your doctor may want to gradually reduce the amount you are taking before stopping it completely. This helps to reduce the chance of your condition becoming worse or keep other unwanted heart problems from happening.

Do not use METROL to treat any other conditions unless your doctor tells you to.

Do not give it to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how METROL 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 cold weather, especially if you will be outside for a long time (for example, when playing winter sports).

METROL, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have blood circulation problems. Beta-blockers tend to decrease blood circulation in the skin, fingers and toes.

Side effects

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

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the 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 side effects are usually mild.

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 or legs
- pain behind the breastbone (different from angina)
- unusual bleeding or bruising

These may be serious side effects of METROL. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using METROL

Storage

Keep the medicine 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.

Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Do not store it, or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking METROL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

METROL comes in 2 strengths of tablets:

- METROL 50 – round, white tablet, scored on one side.
Blister packs of 100 tablets.
- METROL 100 – round, white tablet, scored on one side.
Blister packs of 60 tablets.

Ingredients

The active ingredient in METROL is metoprolol tartrate:

- each METROL 50 tablet contains 50 mg of metoprolol tartrate
- each METROL 100 tablet contains 100 mg of metoprolol tartrate

The tablets also contain:

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

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
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Australian registration numbers:

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METROL 100 mg - AUST R 75834

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