

MISTROM™

Metoprolol tartrate 50 mg and 100 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about MISTROM.

It does not contain all the information that is known about MISTROM. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks 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 MISTROM is used for

MISTROM is used:

1. to lower high blood pressure, also called hypertension;
2. to prevent a type of chest pain, also called angina;
3. after a heart attack; and
4. to prevent migraine headaches.

Hypertension

Everyone has blood pressure. This pressure helps to move your blood around your body. Your blood pressure may be different at various times of the day, depending on how busy you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed. If high

blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

There are usually no symptoms of hypertension. The only way of knowing that you have it is to have your blood pressure checked on a regular basis. You may feel fine and have no symptoms but, if high blood pressure is not treated, it can lead to serious health problems. MISTROM helps to lower your blood pressure.

Angina

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart. The pain of angina is usually brought on by exercise or stress but it can also happen while you are resting.

MISTROM helps to prevent angina from happening. It is not used to treat a sudden attack.

Reducing heart complications after heart attack

After a heart attack there is a chance of developing complications such as an irregular heartbeat (also called an arrhythmia) or another heart attack.

MISTROM helps to prevent these conditions from happening.

Migraine

This is a throbbing headache, usually affecting one side of the head and often accompanied by nausea, vomiting and sensitivity to light.

MISTROM 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 reduces the amount of work that the heart has to do. It also widens the blood vessels in the rest of the body.

MISTROM can be used alone or in combination with other medicines to treat 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.

MISTROM is not recommended for use in children.

MISTROM is only available with a doctor's prescription.

MISTROM is not addictive.

Before you take it

When you must not take it

Do not take MISTROM if you have an allergy to:

- metoprolol (the active ingredient) or to any of the other ingredients of MISTROM listed at the end of this leaflet; and/or
- any other beta-blocker medicines.

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; and
- shortness of breath, wheezing or troubled breathing.

Do not take MISTROM if you have any of the following medical conditions:

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

If you are not sure whether any of the above medical conditions apply to you, check with your doctor.

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

In that case, return it to your pharmacist.

Do not give this medicine to a child.

There is not enough information on its use in children.

Before you start to take it

Tell your doctor if you are allergic to:

- any other medicines, foods, dyes or preservatives; or
- bee or wasp stings.

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

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

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

Your doctor may want to take special precautions if you have any of the above conditions.

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

MISTROM should not be used throughout pregnancy, especially during the first 3 months of pregnancy, unless clearly necessary.

MISTROM 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 breast-feeding or intend to breast-feed.

The active ingredient in MISTROM 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 these things, tell him/her before you take MISTROM.

Taking other medicines

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

Other medicines and MISTROM may interfere with each other.

These medicines include:

- other beta-blocker medicines;
- other medicines used to treat high blood pressure such as calcium channel blockers and clonidine;
- 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;
- other medicines used to treat irregular heart beat (arrhythmias);
- medicines for diabetes;
- guanethidine, a medicine used to treat certain heart conditions;
- some local and general anaesthetics used during surgery;
- monoamine-oxidase inhibitor (MAOI) medicines;
- warfarin, a medicine used to prevent blood clots;
- non-steroidal anti-inflammatory drugs such as COX-2 inhibitors to relieve pain or inflammation;
- cimetidine, a medicine for stomach ulcers;
- some antibiotics (e.g. rifampicin);
- some antivirals (e.g. ritonavir);
- some antihistamines (e.g. diphenhydramine);
- some antidepressant medications (e.g. fluoxetine, paroxetine or bupropion);
- some antifungals (e.g. terbinafine);
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches; and

- dipyridamole, a medicine used to reduce the risk of blood clots.

You may need to take 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 MISTROM.

How to take it

Follow the directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

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

How much to take

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.

Angina:

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

After a heart attack:

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).

How to take it

Swallow the tablets whole with a full glass of water or other liquid.

It does not matter if you take MISTROM before or after food, but it is important to take it in the same way each day. For example, if you always take MISTROM with food, continue taking it with food everyday.

How long to take it

Continue taking MISTROM for as long as your doctor tells you to.

MISTROM helps to control your symptoms but it does not cure your condition. Your doctor will check your progress to make sure the medicine is working and will decide how long your treatment should continue.

Talk to your doctor if you are not sure how long you need to take your medicine for.

If you forget to take it

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

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

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

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

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

If you take too much

Immediately telephone your doctor or Poisons Information Centre (in Australia telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much MISTROM. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

Symptoms of an overdose may include feeling sick and vomiting, bluish skin and nails, very low blood pressure, slow heartbeat, 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 MISTROM, 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 MISTROM, tell your doctor immediately.

There is a chance that MISTROM 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 MISTROM.

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; and
- 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.

MISTROM may change how well your diabetes is controlled. It may also prevent some of the warning signs of low blood sugar, such as fast heartbeat, and may make low blood sugar last longer. The dose of your diabetes medicines 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 MISTROM.

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 MISTROM.

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

Things you must not do

Do not stop taking MISTROM without telling your doctor first.

Your doctor may want to gradually reduce the amount of MISTROM 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 MISTROM to treat any other complaints unless your doctor says you can.

Do not give this medicine to anyone else, even if their symptoms seem to be similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking MISTROM until you know how it affects you.

As with other beta-blocker medicines, MISTROM may cause dizziness, light-headedness or decreased alertness in some people.

If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Be careful to dress warmly during cold weather, especially if you will be outside for a long time.

Like other beta-blocker medicines, MISTROM may make you more sensitive to cold temperatures, especially if you have problems with your blood circulation. These medicines 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 MISTROM.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age, you may have an increased chance of getting 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 side effects and they worry you:

- tiredness, drowsiness, decreased alertness;
- dizziness, spinning sensation (vertigo), light-headedness or fainting;
- headache or other aches and pains;
- difficulty sleeping, nightmares;
- depression or other changes in mood;
- confusion or loss of memory;
- stomach ache or upset, nausea (feeling sick) or vomiting;
- diarrhoea or constipation;

- dry or irritated eyes, blurred vision;
- buzzing or ringing in the ears, or other difficulty hearing;
- dry mouth;
- increased sweating;
- runny or blocked nose;
- problems with sexual function;
- weight gain;
- hair thinning;
- worsening of psoriasis;
- muscle cramps or painful joints;
- a tingling sensation;
- abnormal triglycerides or cholesterol values, or liver function tests during treatment with MISTROM; and
- sleepiness during the day or troubled sleep.

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

- signs of allergy such as swelling of the face, lips or tongue which may cause problems with swallowing or breathing;
- chest tightness, wheezing, rattly breathing;
- shortness of breath, sometimes with tiredness, weakness or reduced ability to exercise;
- swelling of the feet or legs due to fluid build-up;
- coldness, burning, numbness or pain in arms and legs;
- chest pain;
- pain behind the breastbone (different from angina);
- changes in heart rate (fast, slow, irregular);
- yellowing of the skin or eyes (jaundice), sometimes with pain in the abdomen;
- constant "flu-like" symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy);
- unusual bleeding or bruising;
- skin reactions (rash, itching, worsening of psoriasis);
- symptoms of sunburn (redness, itching, swelling, blistering) that

happen much more quickly than normal;

- abnormal thinking or hallucinations (seeing or hearing things that are not there); and
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs, signs of heart disorders.

The above side effects could be serious. You may need urgent medical attention.

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

Other side effects not listed above may happen in some people.

After taking it

Storage

Keep your tablets in the original container until it is time to take them.

Store the tablets in a cool dry place.

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

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

Heat and dampness can destroy some medicines. MISTROM will keep well if it is cool and dry.

Keep this 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.

Disposal

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

Product description

What MISTROM looks like

MISTROM 50 mg tablets are pink, round, biconvex film-coated tablets with 'B' and 'L' separated by a notch break line on one side and '50' embossed on the other side; one carton contains 100 tablets or 10 tablets.

MISTROM 100 mg tablets are white to off white, round, biconvex film-coated tablets with 'B' and 'L' separated by a notch break line on one side and '100' embossed on the other side; one carton contains 60 tablets or 10 tablets.

Ingredients:

MISTROM contains 50 mg or 100 mg of metoprolol tartrate as the active ingredient.

The tablets also contain the following in-active ingredients:

- Lactose;
- Cellulose- microcrystalline;
- Sodium starch glycolate;
- Silica-colloidal anhydrous;
- Croscarmellose sodium;
- Starch pregelatinised – maize;
- Talc – purified;
- Magnesium stearate
- Hypromellose;
- Macrogol 400;
- Titanium dioxide; and
- Iron oxide – red (50 mg only).

Sponsor/Marketing Authorisation Holder



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