

ARX-METOPROLOL

metoprolol tartrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ARX-METOPROLOL.

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 ARX-METOPROLOL 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 ARX-METOPROLOL is used for

ARX-METOPROLOL belongs to a group of medicines called beta-blockers.

ARX-METOPROLOL tablets are used to:

- lower high blood pressure, also called hypertension
- prevent angina
- treat or prevent heart attacks, or reduce your risk of heart complications following a heart attack
- prevent migraine headaches.

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, as well as helping the heart to beat more regularly.

Your doctor will have explained why you are being treated with ARX-METOPROLOL and told you what dose to take.

ARX-METOPROLOL may be used either alone or in combination with other medicines to treat your condition.

Ask your doctor if you have any questions about why ARX-METOPROLOL has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

ARX-METOPROLOL is not addictive

Before you take it

When you must not take it

Do not take ARX-METOPROLOL 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 or you may feel faint.

- **you have asthma, wheezing, difficulty breathing or other lung problems, or have had them in the past**
- **you have a history of allergic problems, including hayfever**
- **you have low blood pressure**
- **you have a very slow heartbeat (less than 45-50 beats/minute)**
- **you have certain other heart Conditions**
- **you have phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines**
- **you have a severe blood vessel disorder causing poor circulation in the arms and legs**
- **you are receiving/having emergency treatment for shock or severely low blood pressure.**

If you are not sure whether any of these apply to you, check with your doctor.

Do not use ARX-METOPROLOL if the expiry date (EXP) printed on the pack has passed 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 ARX-METOPROLOL to children.

The safety and effectiveness of ARX-METOPROLOL in children 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

You must tell your doctor if you have any allergies to:

- metoprolol tartrate or any of the ingredients listed at the end of this leaflet.
- any other medicine, including other beta-blocker medicines
- any other substances, such as foods, preservatives or dyes.

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

- asthma, wheezing, difficulty breathing or other lung problems
- diabetes
- an overactive thyroid gland
- liver problems
- kidney problems
- certain types of angina
- any other heart problems
- phaeochromocytoma, a rare tumour of the adrenal gland
- any blood vessel disorder causing poor circulation in the arms and legs.

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

Like most beta-blocker medicines, ARX-METOPROLOL is not recommended for use during pregnancy.

Tell your doctor if you are breastfeeding or plan to breast-feed.

The active ingredient in ARX-METOPROLOL passes into breast milk and therefore there is a possibility that the breastfed baby may be affected.

If you have not told your doctor about any of these things, tell

them before you take ARX-METOPROLOL.

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 ARX-METOPROLOL, or may affect how well it works. These include:

- other beta-blocker medicines, including beta-blocker eye drops.
- calcium channel blockers or calcium antagonists, medicines used to treat high blood pressure and angina, for example verapamil and diltiazem
- medicines used to treat high blood pressure, for example clonidine, hydralazine, and prazosin
- medicines used to treat abnormal or irregular heartbeat, for example amiodarone, disopyramide and quinidine
- medicines used to treat arthritis, pain, or inflammation, for example indomethacin and ibuprofen
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- medicines used to treat diabetes
- cimetidine, a medicine used to treat stomach ulcers
- medicines used to treat bacterial infections, for example rifampicin
- medicines used to treat depression
- monoamine-oxidase inhibitors (MAOIs).

These medicines may be affected by ARX-METOPROLOL or may affect how well it works. You may need to take different amounts of your medicine, or you may need to

take different medicines. Your doctor will advise you.

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

If you have not told your doctor about any of these things, tell them before you take any ARX-METOPROLOL.

How to take ARX-METOPROLOL

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 ARX-METOPROLOL

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 ARX-METOPROLOL, 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 ARX-METOPROLOL until your doctor tells you to stop.

ARX-METOPROLOL 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 ARX-METOPROLOL (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 ARX-METOPROLOL. 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.

Elderly patients especially need to be monitored to stop their blood pressure falling too far.

If you become pregnant while taking ARX-METOPROLOL, tell your doctor immediately.

If you have a severe allergic reaction to foods, medicines or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that ARX-METOPROLOL may cause allergic reactions to be worse and 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 begin to take ARX-METOPROLOL. This is because your blood pressure has fallen 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. If this problem gets worse or continues, talk to your doctor.

Make sure you drink enough water during exercise and hot weather when you are taking ARX-METOPROLOL, especially if you sweat a lot.

If you do not drink enough water while taking ARX-METOPROLOL, you may feel a bit or light-headed or sick. This is

because your blood pressure is dropping too much. If you continue to feel unwell, tell your doctor.

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

ARX-METOPROLOL may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia).

ARX-METOPROLOL may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicines, including insulin, may need to change.

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

Tell any doctors, dentists, and pharmacists who are treating you that you are taking ARX-METOPROLOL.

If you plan to have surgery (even at the dentist) that needs an anaesthetic, tell your doctor or dentist that you are taking ARX-METOPROLOL.

If you have to have any medical tests while you are taking ARX-METOPROLOL, tell your doctor.

ARX-METOPROLOL may affect the results of some tests.

Things you must not do

Do not stop taking ARX-METOPROLOL without checking with your doctor.

Your doctor may want you to gradually reduce the amount of ARX-METOPROLOL you are taking before stopping completely. This may help reduce the possibility of your condition getting worse.

Do not give ARX-METOPROLOL to anyone else even if they have the same condition as you.

Do not use ARX-METOPROLOL to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how ARX-METOPROLOL affects you.

As with other beta-blocker medicines, ARX-METOPROLOL may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to ARX-METOPROLOL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Be careful drinking alcohol while you are taking ARX-METOPROLOL.

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).

ARX-METOPROLOL, 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 ARX-METOPROLOL.

All medicines can 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.

Ask your doctor to answer any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- headache, tiredness, drowsiness, weakness, or lack of energy
- aches and pains, painful joints
- nausea (feeling sick), vomiting
- stomach upset, diarrhoea or constipation, weight gain
- dry mouth, changes in taste sensation
- difficulty sleeping, nightmares
- mood changes
- confusion, short-term memory loss, inability to concentrate
- increased sweating, runny or blocked nose
- hair loss

These side effects are usually mild.

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

- dizziness, lightheadedness or fainting especially on standing up, which may be due to low blood pressure.
- tingling or "pins and needles"
- coldness, burning, numbness or pain in the arms and/or legs
- skin rash or worsening of psoriasis
- sunburn happening more quickly than usual
- abnormal thinking or hallucinations
- buzzing or ringing in the ears, deafness
- irritated eyes or blurred vision
- sexual problems
- constant "flu-like" symptoms with tiredness or lack of energy
- unusual bleeding or bruising.

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

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

- shortness of breath, being less able to exercise
- swelling of the ankles, feet or legs
- chest tightness, wheezing, noisy breathing, difficulty breathing

- chest pain, changes in heart rate or palpitations
- swelling of the face, lips, tongue or throat which may cause difficulty swallowing or breathing
- yellowing of the skin or eyes (jaundice), generally feeling unwell.

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using ARX-METOPROLOL

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 ARX-METOPROLOL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

Date of last revision: May 2024

What it looks like

ARX-METOPROLOL comes in 2 strengths of tablets:

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

Ingredients

The active ingredient in ARX-METOPROLOL is metoprolol tartrate:

- each ARX-METOPROLOL 50 tablet contains 50 mg of metoprolol tartrate
- each ARX-METOPROLOL 100 tablet contains 100 mg of metoprolol tartrate

The tablets also contain:

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

ARX-METOPROLOL contains sugars as lactose. The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
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Australian registration numbers:

ARX-METOPROLOL 50 mg -
AUST R 75835

ARX-METOPROLOL 100 mg -
AUST R 75834