

ARX-METOPROLOL XL

metoprolol succinate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ARX-Metoprolol XL.

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 XL against the benefits they expect it will have for you.

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

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

What ARX-Metoprolol XL is used for

ARX-Metoprolol XL is used to treat heart failure. It helps to increase survival, reduce hospitalisation and improve symptoms. It is used in combination with other medicines to treat your condition.

ARX-Metoprolol XL 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 helps the heart to beat more regularly.

Your doctor may have prescribed ARX-Metoprolol XL for another reason. Ask your doctor if you have

any questions about why ARX-Metoprolol XL has been prescribed for you.

ARX-Metoprolol XL is not recommended for use in children, as there have been no studies of its effects in children

ARX-Metoprolol XL is available only with a doctor's prescription.

There is no evidence that ARX-Metoprolol XL is addictive.

Before you take ARX-Metoprolol XL

When you must not take it

Do not take ARX-Metoprolol XL if:

- **you are allergic to medicines containing metoprolol 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 or have had asthma difficulty in breathing, wheezing, bronchitis or other lung problems 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 take ARX-Metoprolol XL if the expiry date (Exp.) printed on the pack has passed.

Do not take ARX-Metoprolol XL if the packaging is torn or shows signs of tampering.

Do not give ARX-Metoprolol XL to children.

The safety and effectiveness of ARX-Metoprolol XL 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

Tell your doctor if you have allergies to:

- metoprolol succinate or any of the ingredients listed at the end of this leaflet
- any other medicines, especially other beta-blockers
- any other substances, such as foods, preservatives or dyes.

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

- asthma or other lung problem, even if you had them in the past
- allergic problems, including hayfever
- diabetes
- very slow heart beat (less than 45-50 beats per minute)
- severe blood vessel disorder causing poor circulation in the arms and legs
- liver problems
- kidney problems
- certain types of angina
- any other heart problems
- pheochromocytoma (a rare tumour of the adrenal gland)
- hyperthyroidism (an overactive thyroid gland).

Your doctor may want to take special care if you have any of these conditions.

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

Like most beta-blocker medicines, ARX-Metoprolol XL 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 XL passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

If you have not told your doctor about any of the above, tell them before you start taking ARX-Metoprolol XL.

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 XL, 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 heart problems
- 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
- digoxin, a medicine used to treat heart failure
- medicines used to treat diabetes
- medicines used to treat bacterial infections, for example rifampicin
- cimetidine, a medicine used to treat stomach ulcers
- medicines used to treat depression
- warfarin, a medicine used to prevent blood clots
- monoamine-oxidase inhibitors (MAOIs)

These medicines may be affected by ARX-Metoprolol XL 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 XL.

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

How to take ARX-Metoprolol XL

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 on the pack, ask your doctor or pharmacist for help.

How much to take

The dose varies from patient to patient.

The usual starting dose is half a 23.75 mg or a whole 23.75 mg tablet once a day for one to two weeks. The dose is then usually doubled every second week up to a maximum dose of 190 mg once daily or to the highest tolerated dose.

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines. Your doctor may adjust the dose of other medicines you are taking to obtain the best results for you.

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

DO NOT STOP TAKING ARX-Metoprolol XL SUDDENLY, WITHOUT BEING TOLD BY YOUR DOCTOR.

Stopping ARX-Metoprolol XL suddenly may cause your symptoms to worsen. The dose needs to be reduced slowly over at least 14 days. Your doctor will tell you how to do this.

How to take ARX-Metoprolol XL

Swallow the tablets with a glass of water.

Do not crush or chew the tablets.

If you crush or chew ARX-Metoprolol XL tablets, they will not work as well.

ARX-Metoprolol XL tablets can be broken in half if your doctor has prescribed half a tablet.

If you forget to take ARX-Metoprolol XL

If you miss a dose of ARX-Metoprolol XL and your next dose is more than 12 hours away, take the missed dose right away.

If your next dose is less than 12 hours away take only half the dose.

Take your next dose when you are meant to.

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

If you are not sure what to do, ask your doctor or pharmacist.

How long to take ARX-Metoprolol XL for

To properly control your condition, ARX-Metoprolol XL must be taken every day.

Keep taking ARX-Metoprolol XL for as long as your doctor recommends.

If you take too much ARX-Metoprolol XL (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ARX-Metoprolol XL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ARX-Metoprolol XL, your blood pressure may drop too far. You will feel faint or may faint, and your heart rate will also slow down. You may also have nausea, vomiting and shortness of breath. In extreme cases, serious heart and lung problems may occur.

While you are taking ARX-Metoprolol XL

Things you must do

Visit your doctor regularly and keep all of your appointments so that your doctor can check on your progress.

If you become pregnant while taking ARX-Metoprolol XL, 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 XL 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 XL. 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.

If you feel a worsening of your condition in the early stages of taking ARX-Metoprolol XL

Some people may experience an apparent worsening of their condition in the early stages of treatment with ARX-Metoprolol XL. It is important to tell your doctor if this happens to you, although it is usually temporary. If your condition continues to worsen, you should see your doctor as soon as possible.

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

If you do not drink enough water while taking ARX-Metoprolol XL, you may feel faint 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 XL may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia). ARX-Metoprolol XL may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicines, including insulin, may need to change.

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARX-Metoprolol XL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARX-Metoprolol XL.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking ARX-Metoprolol XL.

Your blood pressure may drop suddenly if ARX-Metoprolol XL interacts with the anaesthetic.

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

ARX-Metoprolol XL may affect the results of some tests.

Things you must not do

Do not stop taking ARX-Metoprolol XL, without checking with your doctor.

Your doctor may want you to gradually reduce the amount of ARX-Metoprolol XL you are taking before stopping completely. This will help reduce the possibility of your condition worsening or other heart complications occurring.

Do not use ARX-Metoprolol XL to treat any other conditions unless your doctor tells you to.

Do not give ARX-Metoprolol XL 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 ARX-Metoprolol XL affects you.

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

Be careful when drinking alcohol while taking ARX-Metoprolol XL.

If you feel dizzy or lightheaded when you take ARX-Metoprolol XL, drinking alcohol may make you feel more dizzy or lightheaded.

Dress warmly during cold weather, especially if you will be outside for a long time (for example when playing winter sports).

ARX-Metoprolol XL, like other beta-blocker medicines, tend to decrease blood circulation in the skin, fingers and toes. It may make you more sensitive to cold weather, 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 XL.

Like all other medicines, ARX-Metoprolol XL 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.

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 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, light headedness or fainting especially on standing up, which may be a sign of 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
- problems with sexual function
- 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.

Tell your doctor immediately or go to Accident and Emergency at

the nearest hospital if you notice any of the following:

- shortness of breath, being less able to exercise
- swelling of the ankles, feet or legs
- chest tightness, wheezing, noisy breathing
- chest pain, changes in heart rate or palpitations
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, which may be signs of a serious allergic reaction
- 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 above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using ARX-Metoprolol XL

Storage

Keep ARX-Metoprolol XL 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.

Keep your tablets in the blister pack until it is time to use them

Do not store ARX-Metoprolol XL or any other medicine in the bathroom or near a sink.

Do not leave ARX-Metoprolol XL 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 XL, 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

ARX-Metoprolol XL comes in 4 strengths of tablets:

- ARX-Metoprolol XL 23.75 – white, oval tablet, scored on both sides
- ARX-Metoprolol XL 47.5 – white, oval tablet, scored on both sides, marked ‘A’ on one side.
- ARX-Metoprolol XL 95 – white, oval tablet, scored on both sides, marked ‘B’ on one side.
- ARX-Metoprolol XL 190 – white, oval tablet, scored on both sides, marked ‘C’ on one side.

ARX-Metoprolol XL 23.75 packs contain 15 tablets. Packs of the other strengths contain 30 tablets.

Ingredients

The active ingredient in ARX-Metoprolol XL is metoprolol succinate.

- each ARX-Metoprolol XL 23.75 tablet contains 23.75 mg of metoprolol succinate
- each ARX-Metoprolol XL 47.5 tablet contains 47.5 mg of metoprolol succinate
- each ARX-Metoprolol XL 95 tablet contains 95 mg of metoprolol succinate
- each ARX-Metoprolol XL 190 tablet contains 190 mg of metoprolol succinate.

The tablets also contain:

- microcrystalline cellulose

- methylcellulose
- glycerol
- maize starch
- ethylcellulose
- magnesium stearate
- Sepifilm LP 770 (ARTG PI No.: 109200)

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

Supplier

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

www.arrotex.com.au

Australian registration numbers:

ARX-METOPROLOL XL 23.75:
AUST R 172299

ARX-METOPROLOL XL 47.5:
AUST R 172300

ARX-METOPROLOL XL 95:
AUST R 172306

ARX-METOPROLOL XL 190:
AUST R 172304

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