

ARX-Lercanidipine Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARX-Lercanidipine?

ARX-Lercanidipine contains the active ingredient [insert active ingredient]. ARX-Lercanidipine is used to lower high blood pressure, which doctors call hypertension.

For more information, see Section [1. Why am I using ARX-Lercanidipine?](#) in the full CMI.

2. What should I know before I use ARX-Lercanidipine?

Do not use if you have ever had an allergic reaction to lercanidipine hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ARX-Lercanidipine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-Lercanidipine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ARX-Lercanidipine?

- ARX-Lercanidipine should be taken at about the same time each day, at least 15 minutes before a meal.

More instructions can be found in Section [4. How do I use ARX-Lercanidipine?](#) in the full CMI.

5. What should I know while using ARX-Lercanidipine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARX-Lercanidipine.• Tell your doctor if you become pregnant while you are taking ARX-Lercanidipine.• If you have an operation, tell the anaesthetist that you are taking this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not take ARX-Lercanidipine with grapefruit or grapefruit juice as these may increase the effects of this medicine.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ARX-Lercanidipine affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool dry place away from sunlight where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using ARX-Lercanidipine?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of these less serious side effects and they worry you: flushing, swelling of the ankles, feet or lower legs, palpitations, headache, dizziness or fainting, gastrointestinal disturbances such as heartburn, nausea, epigastric pain or diarrhoea, fatigue or sleepiness. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects:** angina (chest pain or tightness), increased heartbeat, signs of allergy such as rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARX-Lercanidipine Tablets

Active ingredient(s): *lercanidipine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-Lercanidipine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARX-Lercanidipine.**

Where to find information in this leaflet:

- [1. Why am I using ARX-Lercanidipine?](#)
- [2. What should I know before I use ARX-Lercanidipine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARX-Lercanidipine?](#)
- [5. What should I know while using ARX-Lercanidipine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ARX-Lercanidipine?

ARX-Lercanidipine contains the active ingredient **lercanidipine hydrochloride**. ARX-Lercanidipine belongs to a group of medicines called calcium channel blockers (of the dihydropyridine group).

ARX-Lercanidipine is used to lower high blood pressure, which doctors call hypertension. It works by relaxing some of the blood vessels in the body and reducing resistance to the flow of blood through the blood vessels.

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

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. ARX-Lercanidipine helps lower your blood pressure.

2. What should I know before I use ARX-Lercanidipine?

Warnings

Do not use ARX-Lercanidipine if:

- you are allergic to lercanidipine, any drugs closely related to lercanidipine (such as amlodipine,

felodipine or nifedipine) or any of the ingredients listed at the end of this leaflet.

- you have an obstruction to flow of blood from the heart.
- you have untreated heart failure.
- you have unstable angina (chest pain or tightness at rest or that progressively increases) or you have had a heart attack one month ago or less.
- you have severe liver or kidney disease.
- you are also taking another medicine called ciclosporin.
- you eat grapefruit or drink grapefruit juice.
- you are pregnant or intend to become pregnant.
- you are breastfeeding or plan to breastfeed.
- packaging is torn or shows signs of tampering.
- the tablets show visible sign of deterioration (for example, are broken or discoloured).

Check with your doctor if you:

- take any medicines for any other condition.
- are allergic to any other medicine, any foods, dyes or preservatives, or have a lactose intolerance.
- are taking other drugs for high blood pressure, such as beta-blockers, diuretics, ACE-inhibitors or angiotensin II receptor antagonists.
- have or have ever had any other health problems/medical conditions, including:
 - liver or kidney disease or are on dialysis
 - certain other heart conditions such as:
 - uncontrolled heart failure, an obstruction to flow of blood from the heart, unstable angina (chest pain or tightness at rest or that progressively increases) or you have had a heart attack one month ago or less and/or if you require a pacemaker.

If you have not told your doctor about any of the above or if you are not sure, tell them before you take ARX-Lercanidipine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Like most calcium channel blockers, ARX-Lercanidipine is not recommended for use during pregnancy. Tell your doctor immediately if you become pregnant while you are taking ARX-Lercanidipine.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Like most calcium channel blockers ARX-Lercanidipine is not recommended while you are breastfeeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with ARX-Lercanidipine and affect how it works. These include:

- astemizole
- ciclosporin
- cimetidine (more than 800 mg daily)
- clarithromycin, erythromycin, troleandomycin
- fluoxetine
- itraconazole, ketoconazole
- medicines known as corticosteroids which are used to treat inflammation, allergies and autoimmune conditions
- metoprolol, propranolol
- rifampicin
- ritonavir
- some medicines used to treat an enlarged prostate and improve urinary symptoms
- some medicines used to treat depression
- some medicines used to treat epilepsy such as carbamazepine, phenobarbital (phenobarbitone), phenytoin
- terfenadine

You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines]

Also ask your doctor or pharmacist what to do if you are taking or are about to take the following medicines:

- amiodarone
- digoxin
- midazolam
- quinidine
- Simvastatin
- sotalol

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARX-Lercanidipine.

4. How do I use ARX-Lercanidipine?

How much to take

- Follow the instructions provided and take ARX-Lercanidipine until your doctor tells you to stop.
- The usual dose is one 10 mg tablet taken once daily but may be increased to 20 mg once daily.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take ARX-Lercanidipine

- ARX-Lercanidipine will have the best effect if it is taken at the same time each day at least 15 minutes before meals. This will also help you remember when to take the tablets.

How to take ARX-Lercanidipine

- Swallow ARX-Lercanidipine whole with a glass of water.

If you forget to use ARX-Lercanidipine

ARX-Lercanidipine should be used regularly at the same time each day each day. If you miss your dose at the usual time, but remember within 12 hours from when the dose was due, take it straight away, then continue as normal the next day. Otherwise skip that day's dose but be sure to take the next day's dose when it is due.

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.

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

If you have missed several doses, consult your doctor.

If you use too much ARX-Lercanidipine

If you think that you have used too much ARX-Lercanidipine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much ARX-Lercanidipine it may cause your blood pressure to become too low, you may become dizzy, you may get a headache and you may feel your heart beats become irregular and faster. It may also lead to unconsciousness.

5. What should I know while using ARX-Lercanidipine?

Things you should do

- Use ARX-Lercanidipine exactly as your doctor has prescribed. If you do not follow your doctor's instructions correctly, your blood pressure may not be controlled.
- Be sure to keep all of your doctor's appointments so that your progress can be checked
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking ARX-Lercanidipine.
- If you have an operation, tell the anaesthetist that you are taking this medicine.

Call your doctor straight away if you:

- become pregnant while you are taking ARX-Lercanidipine

Remind any doctor, dentist or pharmacist you visit that you are using ARX-Lercanidipine.

Things you should not do

- Do not give ARX-Lercanidipine to anyone else, even if they have the same condition as you.
- Do not use ARX-Lercanidipine to treat any other complaints unless your doctor tells you to.
- Do not take ARX-Lercanidipine with grapefruit or grapefruit juice as these may increase the effects of this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-Lercanidipine affects you.

ARX-Lercanidipine generally does not cause any problems with your ability to drive a car or operate machinery. However, as with other medicines used to treat high blood pressure, a few people may feel dizzy, light-headed or faint, especially when first taking ARX-Lercanidipine or when starting to take a different amount of medicine.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of ARX-Lercanidipine. Your doctor may ask you to limit or stop your alcohol intake while taking medication to control your blood pressure.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.
- Keep in a cool dry place away from sunlight where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

ARX-Lercanidipine helps most people with high blood pressure, but it may have unwanted side effects in a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>These effects when they occur are usually mild:</p> <ul style="list-style-type: none">• flushing• swelling of the ankles, feet or lower legs• palpitations• headache• dizziness or fainting• gastrointestinal disturbances such as heartburn, nausea, epigastric pain or diarrhoea• fatigue or sleepiness	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>These side effects are usually rare but may be serious and need urgent medical attention:</p> <ul style="list-style-type: none">• angina (chest pain or tightness)• increased heartbeat• signs of allergy such as rash itching or hives on the skin	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ARX-Lercanidipine contains

Active ingredient (main ingredient)	lercanidipine hydrochloride — 10 mg or 20 mg per tablet
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose sodium starch glycollate povidone magnesium stearate polyvinyl alcohol titanium dioxide macrogol 3350 purified talc iron oxide yellow (10 mg only) iron oxide red (20 mg only)
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

What ARX-Lercanidipine looks like

ARX-Lercanidipine 10mg film-coated tablets are yellow, round, biconvex, scored on one side, marked with "L" on the other side (Aust R 172204).

ARX-Lercanidipine 20mg film-coated tablets are pink, round, biconvex, scored on one side, marked with "L" on the other side (Aust R 172206).

ARX-Lercanidipine comes in blister packs of 28 tablets.

Who distributes ARX-Lercanidipine

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 2131

www.arrotex.com.au

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