

Lercanidipine APOTEX

Lercanidipine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about lercanidipine. It does not contain all the available information. It does not replace seeking advice from your doctor or pharmacist.

Please read this leaflet before you start taking this medicine.

If you are helping someone else take this medicine, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking lercanidipine against the benefits this medicine is expected to 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 lercanidipine is used for

The name of your medicine is Lercanidipine APOTEX, which is also known as lercanidipine. Lercanidipine belongs to a group of medicines called calcium channel blockers (of the dihydropyridine group).

Lercanidipine lowers 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.

Lercanidipine helps lower your blood pressure.

Lercanidipine cannot be obtained without a doctor's prescription.

There is no evidence that lercanidipine is addictive.

Before you take lercanidipine

When you must not take it

Do not take lercanidipine if you have an allergy to:

- lercanidipine or any of the ingredients listed at the end of this leaflet
- any drugs closely related to lercanidipine (such as amlodipine, felodipine or nifedipine)

Do not take lercanidipine if you:

- have severe liver or kidney disease
- are also taking another medicine called cyclosporin

Ask your doctor or pharmacist if you are not sure.

Do not take lercanidipine if you are pregnant or intend to become pregnant.

Like most calcium channel blockers, lercanidipine is not recommended for use during pregnancy.

Tell your doctor immediately if you become pregnant while you are taking lercanidipine.

Do not take lercanidipine if you are breast-feeding or plan to breast-feed.

Like most calcium channel blockers lercanidipine is not recommended while you are breast-feeding.

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

Do not take this medicine if the tablets show visible sign of deterioration (for example, are broken or discoloured).

Do not take this medicine if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work (as well).

If you are not sure whether you should start taking lercanidipine, talk to your doctor.

Do not give lercanidipine to a child under the age of 18 years.

Lercanidipine is not recommended for use in children.

Before you start to take it

You must tell your doctor:

1. if you are allergic to any other medicine or any foods, dyes or preservatives.
2. if you are taking other drugs for high blood pressure, such as beta-blockers, diuretics, ACE-inhibitors or angiotensin II receptor antagonists.
3. if you 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 progressively increasing) 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 this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with the way lercanidipine works, or may be affected by lercanidipine. These include:

- ritonavir, cyclosporin, ketoconazole, itraconazole, erythromycin, fluoxetine, cimetidine (more than 800 mg daily).

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: phenytoin, carbamazepine, rifampicin, amiodarone, quinidine, digoxin, simvastatin, metoprolol or propranolol.

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

How to take lercanidipine

How much to take

Follow all directions given to you by your doctor carefully.

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

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.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take the tablet at about the same time each day, at least 15 minutes before a meal.

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 long to take it

Lercanidipine helps control your condition, but does not cure it. Therefore you must take lercanidipine every day. Continue taking the tablets for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose 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 you are not sure about what to do, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that 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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident & Emergency at your nearest hospital, if you think that you or anyone else may have taken too much lercanidipine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places/services handy.

If you take too much lercanidipine it may cause your blood pressure to become too low and you may feel your heart beats become irregular and faster. It may also lead to unconsciousness.

While you are taking lercanidipine

Things you must do

Take 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 become pregnant while you are taking lercanidipine, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking lercanidipine.

Tell all other doctors, dentists and pharmacists who are treating you that you are taking lercanidipine.

If you have an operation, tell the anaesthetist that you are taking this medicine.

Things you must not do

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

Do not use lercanidipine 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 lercanidipine affects you.

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 lercanidipine or when starting to take a different amount of medicine. Your doctor may also ask you to limit or stop your alcohol intake while taking medicines to control your blood pressure, such as lercanidipine, as alcohol may increase these effects.

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

As with some medicines used to treat high blood pressure such as lercanidipine, you should avoid drinking grapefruit juice as grapefruit juice may increase the effects of these medicines.

Side effects

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

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. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Possible side effects include:

- flushing
- swelling of the ankles, feet or lower legs
- headache
- dizziness
- gastrointestinal disturbances such as heartburn, nausea, epigastric pain or diarrhoea
- fatigue or sleepiness

These effects when they occur are usually mild. However, should you experience any of these or other undesirable effects not mentioned above, you should consult your doctor or pharmacist.

Ask your doctor or pharmacist to answer any questions you may have.

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

- angina (chest pain or tightness)
- increased heart beat

- signs of allergy such as rash, itching or hives on the skin

These side effects are usually rare but may be serious and need urgent medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking lercanidipine

Storage

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 it in a cool dry place away from sunlight 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.

Keep it 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 the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

This medicine is available in 10 mg or 20 mg tablets.

The 10 mg tablets are yellow and round with a score line on one side and an "L" on the other.

The 20 mg tablets are round and pink with a score line on one side and an "L" on the other.

This medicine comes in blister packs of 28 tablets.

Ingredients

Active Ingredient

Lercanidipine hydrochloride 10 mg or 20 mg per tablet.

Excipient Ingredients

Lactose, cellulose microcrystalline, sodium starch glycollate, povidone, magnesium stearate, polyvinyl alcohol, purified talc, titanium dioxide, macrogol, iron oxide yellow and iron oxide red (20mg only).

The tablets are free from gluten, glucose and sucrose.

Australian Registration Number:

10 mg blister pack: 172204

20 mg blister pack: 172206

Sponsor

Medis Pharma Pty Ltd

1002/53 Walker St

North Sydney NSW 2060

Distributor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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