

ZIRCOL 10 and ZIRCOL 20

lercanidipine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZIRCOL 10 and ZIRCOL 20. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZIRCOL 10 or ZIRCOL 20 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 ZIRCOL 10 and ZIRCOL 20 are used for

The name of your medicine is ZIRCOL 10 or ZIRCOL 20, which is also known as lercanidipine.

ZIRCOL 10 and ZIRCOL 20 belong to a group of medicines called calcium channel blockers (of the dihydropyridine group).

ZIRCOL 10 and ZIRCOL 20 lower high blood pressure, which is also called 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. ZIRCOL 10 and ZIRCOL 20 help lower your blood pressure.

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.

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

There is no evidence that this medicine is addictive.

Before you take ZIRCOL 10 or ZIRCOL 20

When you must not take it

Do not take ZIRCOL 10 or ZIRCOL 20 if you have an allergy to:

- lercanidipine
- any of the ingredients listed at the end of this leaflet
- any other similar medicines such as amlodipine, felodipine or nifedipine

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

Do not take this medicine if you:

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

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

Like most calcium channel blockers, ZIRCOL 10 and ZIRCOL 20 are not recommended for use during pregnancy.

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

Like most calcium channel blockers ZIRCOL 10 and ZIRCOL 20 are not recommended while you are breast-feeding.

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

It is not recommended for use in children.

Do not take this medicine after the expiry date printed on the pack 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 take the tablets if they show visible sign of deterioration (for example, are broken or discoloured).

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 any other medicine, foods, dyes or preservatives

Tell your doctor if you are taking other drugs for high blood pressure, such as beta-blockers, diuretics, ACE-inhibitors or angiotensin II receptor antagonists

Tell your doctor if you have or have ever had any other medical conditions:

- 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 in the chest at rest or progressively increasing) or you have had a heart attack one month ago or less and/or if you require a pacemaker

Tell your doctor immediately if you become pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking ZIRCOL 10 or ZIRCOL 20.

Taking other medicines

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

Some medicines may interfere with the way ZIRCOL 10 or ZIRCOL 20 work, or may be affected by ZIRCOL 10 or ZIRCOL 20. These include:

- ritonavir, a medicine used to treat HIV/AIDS

- ciclosporin, a medicine used to prevent the rejection of an organ transplant
- ketoconazole, itraconazole, medicines used to treat fungal infections
- erythromycin, a medicine used to bacterial infections
- fluoxetine, a medicine used to treat depression and obsessive compulsive disorder
- cimetidine (more than 800 mg daily), a medicine used to treat gastroesophageal reflux disease

These medicines may be affected by ZIRCOL 10 or ZIRCOL 20 or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

- **phenytoin, carbamazepine, medicines used to treat epilepsy**
- **rifampicin, a medicine used to treat bacterial infections**
- **amiodarone, quinidine, medicines used to treat ventricular tachycardia (a fast heart beat)**
- **digoxin, a medicine used to treat heart failure and irregular heart beats**
- **simvastatin, a medicine used to lower cholesterol**

- **metoprolol, propranolol, medicines used to treat high blood pressure and other conditions**

Your doctor and pharmacist have more information on medicine to be careful with or avoid while taking this medicine.

How to take ZIRCOL 10 and ZIRCOL 20

How much to take

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 box, ask your doctor or pharmacist for help.

The usual dose is one 10 mg tablet taken once daily, but may be increased to 20 mg once daily.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

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

Taking it at the same time each day and at least 15 minutes before a meal will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If you forget to take your medicine but remember within 12 hours from when you were meant to take the dose, take it straight away and then continue as normal the next day.

Otherwise 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 that you missed.

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

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

If you have missed several doses, contact your doctor.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident & Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ZIRCOL 10 or ZIRCOL 20. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ZIRCOL 10 or ZIRCOL 20 it may cause your blood pressure to become too low and you may feel your heart beat become irregular and faster. It may also lead to unconsciousness.

While you are using ZIRCOL 10 or ZIRCOL 20

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ZIRCOL 10 or ZIRCOL 20.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take ZIRCOL 10 or ZIRCOL 20 to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how ZIRCOL 10 or ZIRCOL 20 affects you.

ZIRCOL 10 and ZIRCOL 20 generally do 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 ZIRCOL 10 or ZIRCOL 20 or when starting to take a different amount of this medicine.

Your doctor may also ask you to limit or stop your alcohol intake while taking medicines to control your blood pressure,

such as ZIRCOL 10 or ZIRCOL 20, 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 ZIRCOL 10 and ZIRCOL 20, 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 ZIRCOL 10 or ZIRCOL 20.

This medicine 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 attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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.

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.

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

Other side effects not listed above may also occur in some people.

After using ZIRCOL 10 and ZIRCOL 20

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store ZIRCOL 10 or ZIRCOL 20 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 this medicine the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ZIRCOL 10 and ZIRCOL 20 are available in 10mg or 20mg tablets.

The 10mg tablets are yellow and round with a score line across the middle.

The 20mg tablets are round and pink.

ZIRCOL 10 and ZIRCOL 20 come in packs of 7 (sample) or 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

- hypromellose
- purified talc
- titanium dioxide
- macrogol 6000
- ferric oxide (yellow-10mg, red-20mg).

ZIRCOL 10 and ZIRCOL 20 do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

ZIRCOL 10 and ZIRCOL 20 are supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

10 mg - AUST R 295935

20 mg - AUST R 295936

This leaflet was prepared in October 2018

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