Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zircol.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

Please read this leaflet before you start taking Zircol.

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

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

The name of your medicine is Zircol, 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. Zircol helps lower your blood pressure.

Zircol cannot be obtained without a doctor's prescription.

There is no evidence that Zircol is addictive.

Before you take Zircol

When you must not take it

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

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

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

Do not take Zircol if you are breast-feeding or plan to breastfeed.

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

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

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

Do not take Zircol 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 Zircol, talk to your doctor.

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

Zircol is not recommended for use in children.

Before you start to take it

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- 2. you are taking other drugs for high blood pressure, such as beta-blockers, diuretics, ACEinhibitors or angiotensin II receptor antagonists.
- 3. 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, please do so before you take Zircol.

Taking other medicines

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

Some medicines may affect the way others work, or may be affected by Zircol. 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 Zircol.

Use in children

There is not enough information to recommend the use of Zircol in children.

How to take Zircol

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 tablets whole with a glass of water.

When to take it

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

Zircol 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

Zircol helps control your condition, but does not cure it. Therefore you must take Zircol 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 Zircol. 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 Zircol 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 Zircol

Things you must do

Use Zircol 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 Zircol, tell your doctor.

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

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

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

Things you must not do

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

Do not use Zircol 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 Zircol affects you.

Zircol 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 Zircol 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 Zircol, 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, you should avoid drinking grapefruit juice as grapefruit juice may increase the effects of these medicines.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid secondhand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 eating plenty of vegetables and fruit:
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderateintensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

 Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.

- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

Zircol 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 Zircol

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 25°C.

Do not store Zircol or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or 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 is available in 10mg or 20mg tablets

 The 10mg tablets are a yellowish brown, film coated, round, biconvex tablet debossed with "LR over 1" on one side of the tablet and a deep break line on the other side. The 20mg tablets are a pink, film coated, round, biconvex tablet debossed with "LR over 2" on one side of the tablet and a deep break line on the other side.

Zircol is available in blister packs of 28 tablets.

Ingredients

The active ingredient in Zircol is lercanidipine hydrochloride.

The tablets also contain:

- lactose
- microcrystalline cellulose
- crospovidone
- povidone
- magnesium stearate
- Opadry Complete Film Coating System 03F82659 Yellow (Proprietary Ingredient Number 106579) (10mg tablet)
- Opadry Complete Film Coating System 03F84645 Pink (Proprietary Ingredient Number 106580) (20mg tablet)

Supplier

Zircol is supplied 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.alphapharm.com.au

Medical Information Phone: 1800 028 365

Australian registration numbers:

Zircol Lercanidipine 10mg blister pack AUST R 166273 Zircol Lercanidipine 20mg blister pack AUST R 166274

This leaflet was prepared on 7 February 2011.