

OZLODIP®

Amlodipine Besylate Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about **OZLODIP** (amlodipine besylate) tablets.

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 **OZLODIP** against the benefits it is expected to have for you.

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

Keep this leaflet with this medicine.

You may need to read it again.

What OZLODIP is used for

OZLODIP is used to reduce high blood pressure (hypertension). Usually there are no symptoms of hypertension. The only way of knowing you have hypertension is to have your blood pressure regularly checked. If high blood pressure is not treated it can lead to serious health problems.

OZLODIP is also used to treat angina pectoris. Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck, and sometimes to the shoulders and back. The pain of angina is due to a lack of oxygen to the heart.

OZLODIP is not used for the relief of a sudden attack of angina. Your doctor will give you other medication to treat this.

OZLODIP belongs to a group of medicines called *calcium channel blockers* or *calcium ion antagonists*. These medicines work by widening your blood vessels, making it easier for your heart to pump blood around the body and help increase the supply of blood and oxygen to your heart. *Calcium channel blockers* do not alter the amount of calcium in your blood or bones.

If you have any questions about why OZLODIP has been prescribed for you, ask your doctor.

Your doctor may have prescribed **OZLODIP** for another purpose.

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

Use in Children

This medicine is not recommended for use in children.

Before you take OZLODIP

When you must not take it

Do not take OZLODIP if you have an allergy to:

- OZLODIP, or any other medicine containing amlodipine (for example Norvasc).
- other calcium blockers such as those listed below:

felodipine (Plendil ER, Felo ER, Agon SR, Felodur ER), nifedipine (Adalat, Adalat Oros, Adexin XL, Nifehexal, Nyefax) or lercanidipine (Zanidip)

Not all brands are given. Check with your doctor or pharmacist if you are unsure.

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, difficulty in breathing or wheezing, swelling of the face, lips, tongue or other parts of the body or a rash, itchiness or hives on the skin.

Do not breast-feed if you are taking this medicine as it is unknown whether the active ingredient in OZLODIP passes into breast milk or if your baby may be affected.

Do not take this medicine if:

- the packaging shows signs of tampering or is torn.
- the expiry date marked on the packaging has passed, even though the tablets may look alright.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be taking OZLODIP, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any foods, dyes, preservatives or any other medicines.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease such as heart failure
- liver problems

Tell your doctor if you are pregnant or intend to become pregnant while taking OZLODIP.

This medicine may affect the developing baby if you take it during pregnancy. Your doctor will discuss the possible risks and benefits of taking this medicine.

If you have not told your doctor about any of the above, please do so before you start taking OZLODIP.

Taking other medicines

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

Some medicines may be affected by **OZLODIP** or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- other medicines used to treat angina, such as diltiazem
- some antibiotics, such as erythromycin or rifampicin
- some antifungals, such as ketoconazole or itraconazole
- anti-proteases, medicines used to treat HIV infection, such as ritonavir
- St John's Wort
- grapefruit or grapefruit juice

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

How to take OZLODIP

Take **OZLODIP** exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. This may be different from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to take

The usual initial dose of **OZLODIP** is one 5-mg tablet each day. Your doctor may increase this to one 10-mg tablet each day.

Your doctor may prescribe another dose of **OZLODIP** depending on your condition and how you respond to this medicine.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take your tablet at about the same time each day, either morning or evening. Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take it.

OZLODIP can be taken with or without food.

How long to take it

You must take **OZLODIP** every day. Continue taking your medicine for as long as your doctor tells you.

This medicine does not cure your condition but it helps to control it. It is vital that you keep taking this medicine even if you are feeling well.

If you forget to take it

If you miss a dose and it is less than 12 hours from when you should take it, 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.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of getting an unwanted side effect.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 Australia only) or the National Poisons and Hazardous Chemicals Information Centre (0800 POISON – 0800 764 766 New Zealand only) for advice, or go to accident and emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much OZLODIP.

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 many tablets, you may feel dizzy, lightheaded or faint and have an irregular heart beat.

While you are using OZLODIP

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking **OZLODIP**.

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking **OZLODIP**.

If you become pregnant while taking **OZLODIP** tell your doctor immediately.

Take **OZLODIP** tablets exactly as your doctor tells you to.

Visit your doctor regularly for check-ups.

Things you must not do

Do not take OZLODIP to treat any other conditions unless your doctor says to.

Do not give this 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.

Things to be careful of

Be careful driving or operating machinery until you know how OZLODIP affects you. **OZLODIP** may cause dizziness or drowsiness in some people and affect alertness.

If this occurs, do not drive, operate machinery or do things that could be dangerous.

Things that would be helpful for your high blood pressure or angina:

Some self-help measures suggested below may assist your condition. Your doctor or pharmacist can provide you more information about these measures.

Talk to your doctor about these for more information:

- **Weight:** Your doctor may suggest losing some weight. Some people may need a dietician to plan a suitable diet to help with weight loss.
- **Exercise:** Regular exercise helps lower blood pressure and strengthens the heart. It is important not to overdo it. Before commencing regular exercise you should consult your doctor who will suggest the most suitable exercise for you. If you feel uncomfortable when exercising or experience symptoms such as unusual chest pain or breathlessness see your doctor.
- **Alcohol:** Your doctor may advise you to limit your alcohol intake.
- **Salt:** Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt at the table or in cooking.
- **Smoking:** Your doctor may advise you to stop smoking or at least cut down.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking OZLODIP. OZLODIP helps most people but it may have some 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.

It can be difficult to tell whether side effects are the result of taking OZLODIP, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

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

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

- swelling of the ankles, feet, face or hands
- headache
- dizziness
- flushing
- palpitations
- tiredness
- drowsiness or sleepiness
- stomach pain or nausea

These are the more common side effects of **OZLODIP**.

Tell your doctor if you experience any of the following:

- indigestion
- unusual tiredness or weakness

- muscle cramps or aches
- sexual problems
- swollen gums
- constipation
- weight gain
- sleeplessness
- feeling nervous, depressed or moody
- changes in vision or sight
- loss or thinning of hair
- ringing in the ears

These may or may not be due to OZLODIP but you should tell your doctor if they worry you.

Tell your doctor immediately if you notice any of the following:

- changes in heart beat (either fast or slow)
- chest pain
- dizziness or light-headedness on standing up from a sitting or lying position
- shortness of breath
- symptoms of allergy such as skin rash and/or itching, hives, fainting, swelling of the limbs, face, mouth or throat which may cause difficulty in swallowing or breathing
- symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urine

These may be serious side effects that may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you notice any other symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you do not understand anything on this list.

If you are 65 years or older, you should be especially careful while taking OZLODIP. Report any side effects promptly to your doctor. Some people in this age group may be more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness.

After using OZLODIP

Storage

Keep OZLODIP where children cannot reach it. A secured locked cupboard at least one-and-a-half metres above the ground is a good place for storage of medicines.

Keep your tablets in the pack until it is time to take them. If you take your tablets out of the pack they may not keep as well.

Keep your tablets in a cool dry place where temperatures stay below 25°C. Protect from light.

Do not store OZLODIP or any other medicine in the bathroom or near a sink. Do not leave your medicines on a window sill or in the car.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking **OZLODIP**, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

OZLODIP 5 mg are white to off-white, capsule-shaped tablets, debossed with 'A' and '13' on either side of breakline on one side and breakline on other side. Available in packs of 30 tablets.

OZLODIP 10 mg are white to off-white, capsule-shaped tablets, debossed with 'A' and '14' on either side of breakline on one side and breakline on other side. Available in packs of 30 tablets.

Ingredients

Active ingredient

OZLODIP 5 mg tablets - 5 mg of amlodipine as amlodipine besylate

OZLODIP 10 mg tablets - 10 mg of amlodipine as amlodipine besylate

Inactive ingredients

Microcrystalline cellulose, mannitol, sodium starch glycollate (Type A), colloidal anhydrous silica and magnesium stearate

Australian Registration Numbers

OZLODIP 5 mg tablets: AUST R 141652

OZLODIP 10 mg tablets: AUST R 142081

Sponsor

OZLODIP tablets are supplied in Australia by:

Ranbaxy Australia Pty. Ltd
Suite 4.02, Building D, Level 4
12-24 Talavera Road
North Ryde, NSW 2113
Australia

OZLODIP tablets are supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
Central Park Drive, Lincoln
P O Box 45 027, Auckland 0651
New Zealand

Phone: (09) 835 0660
Fax: (09) 835 0665

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