

PLENDIL® ER

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 PLENDIL ER?

PLENDIL ER contains the active ingredient felodipine. PLENDIL ER is used to treat high blood pressure, also called hypertension.

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

2. What should I know before I use PLENDIL ER?

Do not use if you have ever had an allergic reaction to felodipine 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 PLENDIL ER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PLENDIL ER 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 PLENDIL ER?

- The usual starting dose of PLENDIL ER is one 2.5 mg or 5 mg tablet taken once daily.
- Swallow PLENDIL ER tablets whole and wash them down with a glass of water. They must not be divided, crushed or chewed.
- It does not matter if you take PLENDIL ER with food or not, but you must not take it with grapefruit juice.

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

5. What should I know while using PLENDIL ER?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using PLENDIL ER.

	<ul style="list-style-type: none"> • 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 should not do	<ul style="list-style-type: none"> • Do not stop taking PLENDIL ER unless you have discussed it with your doctor. • Do not take PLENDIL ER with grapefruit juice.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how PLENDIL ER affects you. When you start taking PLENDIL ER, whether you are changing from another medicine for high blood pressure or not, you may feel dizzy or faint due to the drop in your blood pressure.
Drinking alcohol	<ul style="list-style-type: none"> • Be careful when drinking alcohol while you are using PLENDIL ER.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- Keep it in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include headache, swelling of the ankles, dizziness, flushing, palpitations (feeling of heart pounding), fatigue (tiredness), nausea, stomach pain, frequent urination, pins and needles or muscular pain. However, some side effects may need medical attention. These include skin rash, fainting, chest pain, rapid heart beat or allergic reaction such as swelling of the face, tongue or back of the throat or difficulty when breathing.

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.

PLENDIL® ER

Active ingredient: *Felodipine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PLENDIL ER. **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 PLENDIL ER.**

Where to find information in this leaflet:

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

1. Why am I using PLENDIL ER?

PLENDIL ER contains the active ingredient felodipine. Felodipine belongs to the family of medicines known as calcium channel blockers. These medicines do not change the way the body takes in calcium from food.

PLENDIL ER is used to treat high blood pressure, also called hypertension.

PLENDIL ER lowers blood pressure by dilating (expanding) small blood vessels, letting the blood pumped around the body more easily.

Your doctor will have explained why you are being treated with PLENDIL ER and told you what dose to take.

The ER in PLENDIL ER stands for Extended Release. This means that the tablets are designed to work over a 24 hour period.

2. What should I know before I use PLENDIL ER?

Warnings

Do not use PLENDIL ER if:

- you are allergic to felodipine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have uncompensated heart failure
- you have acute myocardial infarction
- you have cardiac valvular obstruction
- you have dynamic cardiac outflow obstruction
- you have unstable angina pectoris

If you are not sure whether you have any of these conditions, ask your doctor.

Check with your doctor if you:

- have any allergies to any other medicines or foods
- have any medical conditions such as any heart problem including angina or liver problems
- take any medicines for any other condition
- are lactose intolerant. PLENDIL ER tablets contain lactose.
- have any questions about how you should be using your PLENDIL ER.

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

Do not use PLENDIL ER if you are pregnant or likely to become pregnant. Ask your doctor about the risks and benefits involved.

PLENDIL ER should not be used during pregnancy. It may affect your baby if you take it during pregnancy.

Tell your doctor as soon as possible if you become pregnant while using PLENDIL ER.

Tell your doctor if you are breastfeeding or intend to breastfeed before you take PLENDIL ER.

Your baby can take in PLENDIL ER from breast milk if you are breastfeeding, but it is unlikely to affect the infant when the mother is taking doses within the normal

range for her treatment. Your doctor can discuss the risks and benefits involved.

Use in children

Do not give PLENDIL ER to children. There is no information on its use in children.

3. What if I am taking other medicines?

Some medicines and PLENDIL ER may interfere with each other. These include:

- cimetidine - a medicine used to treat stomach ulcers or heartburn
- medicines used to treat infections such as erythromycin and rifampicin
- treatment with PLENDIL ER may affect the level of tacrolimus (a medicine given to prevent the body from rejecting a transplanted organ, eg. kidney or liver) in your blood
- medicines used to treat fungal infections such as itraconazole and ketoconazole
- medicines used to treat epilepsy such as phenytoin and carbamazepine
- medicines used to help you sleep such as barbiturates
- St John's Wort - a herbal remedy used to treat mood disorders.

Do not take PLENDIL ER with grapefruit juice. Grapefruit juice may increase the effect of PLENDIL ER.

These medicines may be affected by PLENDIL ER or may affect the way PLENDIL ER works. You may need different amounts of your medicines, or may need to take different medicines.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are taking other drugs which lower blood pressure, your doctor may need to change the dose of them to obtain the best results for you.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. If you are unsure about any medicine you are taking, you should check with your doctor or pharmacist.

4. How do I use PLENDIL ER?

How much to take

- The usual starting dose of PLENDIL ER is one 2.5 mg or 5 mg tablet taken once daily.
- Your doctor will check your progress and if needed, increase your dose of PLENDIL ER. Sometimes the dose will be as high as 20 mg (two 10 mg tablets) once a day.
- **If you have to take more than one tablet, you must take them together.**

When to take

- **Swallow PLENDIL ER tablets whole and wash them down with a glass of water. They must not be divided, crushed or chewed.** If they are broken or crushed they will not work over 24 hours as they are supposed to.
- **It does not matter if you take PLENDIL ER with food or not, but you must not take it with grapefruit juice.** Grapefruit juice may increase the effect of PLENDIL ER.

How long to take

Take PLENDIL ER for as long as your doctor tells you to. PLENDIL ER must be taken every day.

PLENDIL ER helps control your high blood pressure, but does not cure it.

Treatment of high blood pressure is necessary in most people for the rest of their lives. Ask your doctor to explain the reasons for this.

If you forget to use PLENDIL ER

If you forget a dose, take it as soon as you remember, as long as it is more than 12 hours before the next dose is due.

If it is less than 12 hours until 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 when to take your medicine, ask your pharmacist for some hints.

If you use too much PLENDIL ER

If you think that you have used too much PLENDIL ER, 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 PLENDIL ER you may experience a headache, a slow heartbeat, very low blood pressure, dizziness, tiredness or feel sick (nausea).

5. What should I know while using PLENDIL ER?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PLENDIL ER.

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

Call your doctor straight away if you:

- **become pregnant while taking this medicine**

Remind any doctor, dentist or pharmacist you visit that you are using PLENDIL ER.

Things you should not do

- Do not stop taking PLENDIL ER unless you have discussed it with your doctor
- Do not take PLENDIL ER with grapefruit juice. Grapefruit juice may increase the effect of PLENDIL ER
- Do not use this medicine to treat any other complaint unless your doctor tells you to
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PLENDIL ER affects you.

When you start taking PLENDIL ER, whether you are changing from another medicine for high blood pressure or not, you may feel dizzy or faint due to the drop in your blood pressure.

Drinking alcohol

Be careful when drinking alcohol while you are using PLENDIL ER. Tell your doctor if you drink alcohol.

Looking after your medicine

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

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 window sills.

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?

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.

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

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
<ul style="list-style-type: none">• headache• swelling of the ankles• dizziness• flushing• palpitations (feeling of heart pounding)• fatigue (tiredness)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These side effects usually go away or get less with time. If they do occur, it mostly happens at the beginning of treatment, or when the dose is increased.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● nausea (feeling sick) ● frequent urination ● impotence / sexual dysfunction ● stomach pain ● pain, swelling or redness in your gums ● fever ● increased sensitivity of the skin to sunlight ● sensation of burning, prickling, numbness, "pins and needles" ● pain in joints or muscular pain 	<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
<ul style="list-style-type: none"> ● Allergic Reaction: ● swelling of the face, tongue or back of the throat ● harsh sounds or difficulty when breathing <p>Others:</p>	<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. You</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • skin rash • fainting • chest pain • rapid heart beat 	<p>may need urgent medical attention.</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 PLENDIL ER contains

Active ingredient (main ingredient)	felodipine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● hydrogenated castor oil● propyl gallate● hypromellose● aluminium sodium silicate● microcrystalline cellulose● lactose● sodium stearyl fumarate● hyprolose● macrogol 6000● titanium dioxide● iron oxide yellow● iron oxide red (5 mg and 10 mg tablet only)● Carnauba wax
Potential allergens	lactose

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

What PLENDIL ER looks like

PLENDIL ER tablets are registered in 3 strengths:

- PLENDIL ER 2.5 mg tablets are round, yellow tablets marked "A" over "FL" on one side and "2.5" on the other. [AUST R 51774]
- PLENDIL ER 5 mg tablets are round, pink tablets marked "A" over "Fm" on one side and "5" on the other. [AUST R 51775]
- PLENDIL ER 10 mg tablets are round, reddish-brown tablets marked "A" over "FE" on one side and "10" on the other. [AUST R 51776]

All strengths are available in blister packs* of 30 tablets.

*not all presentations might be available in Australia.

Who distributes PLENDIL ER

AstraZeneca Pty Ltd
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Telephone:- 1800 805 342

This leaflet was prepared on 06 April 2023.

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