

FELODUR[®] ER

Felodipine

Consumer Medicine Information

Name of consumer

Address of consumer

What is in this leaflet

This leaflet answers some of the common questions people ask about **FELODUR ER**. It does not contain all the information that is known about **FELODUR ER**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **FELODUR ER** 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 FELODUR ER is for

FELODUR ER lowers blood pressure by dilating (expanding) small blood vessels away from the heart, letting the blood be pumped around the body more easily.

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

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

FELODUR ER contains felodipine, which 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.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

FELODUR ER is not addictive

Before you use FELODUR ER

When you must not use it

Do not use FELODUR ER if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

FELODUR ER should not be used during pregnancy unless your doctor thinks that it is the best drug for you. It may affect your baby if you take it during pregnancy.

Your baby can take in very small amounts of **FELODUR ER** from breast milk if you are breastfeeding, but it is unlikely that the amount available to the baby will do any harm.

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

Do not use after the use by (expiry) date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use FELODUR ER if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Before you start to use it

You must tell your doctor if:

- 1. you have any allergies to**
 - any ingredients listed at the end of this leaflet
 - any other medicine used to treat high blood pressure
 - any other substances

If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing or feel faint.

- 2. you have any of these medical conditions**
 - any heart problem, including angina

It may not be safe for you to take **FELODUR ER** if you have any of these conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- cimetidine – a medicine used to treat stomach ulcers or heartburn
- erythromycin – an antibiotic
- treatment with **FELODUR ER** may affect the level of tacrolimus (a medicine given to prevent the body from rejecting a transplanted organ, e.g. kidney or liver) in your blood.
- medicines used to treat fungal infections
- medicines used to treat epilepsy
- medicines used to help you sleep
- any medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way **FELODUR ER** works.

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

If you have not told your doctor about any of these things, tell them before you take any **FELODUR ER**.

Taking FELODUR ER

How much to take

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.

The usual starting dose is a 2.5 or 5 mg tablet taken once daily.

Your doctor will check your progress and if it is needed, increase your dose of **FELODUR ER**. Sometimes the dose will be as high as 20mg a day.

If you have to take more than one tablet, you must take them together.

Swallow FELODUR 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 doesn't matter if you take FELODUR ER with food or not, but you must not take it with grapefruit juice. Grapefruit juice, but not other fruit juices, may increase the effect of **FELODUR ER**.

If you forget to take it

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

Don't double the dose.

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

How long to take 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.

Overdose

Telephone your doctor, the Poisons Information Centre (13 11 26) or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too much FELODUR ER even if there are no signs of discomfort or poisoning.

If you take too much **FELODUR ER** you will probably get a headache and feel sick (nausea), dizzy and very tired.

While you are using it

Things you must not do

Do not take FELODUR ER with grapefruit juice. Grapefruit juice, but not other fruit juices, may increase the effect of **FELODUR ER**.

Do not stop taking FELODUR ER unless you have discussed it with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how FELODUR ER affects you. When you start taking **FELODUR 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.

Be careful when drinking alcohol while you are using FELODUR ER.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Side effects

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

FELODUR ER 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.

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

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

- headache
- fluid in the legs
- dizziness
- flushing
- nausea (feeling sick)
- palpitations (rapid heart beat)
- fatigue (tiredness)
- fever
- frequent urination
- impotence / sexual dysfunction
- stomach pain
- pain, swelling or redness in your gums

These are all mild side effects of **FELODUR ER**.

They are more likely if you are taking a high dose. They 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.

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

- skin rash

This can be a serious side effect. You may need urgent medical attention

Serious side effects are rare.

If any of the following happen, stop taking FELODUR ER and tell your doctor immediately or go to casualty at your nearest hospital.

- swelling of the face, tongue or back of the throat
- harsh sounds when breathing

These are very serious side effects. If you have them, you may have had a serious (allergic) reaction to **FELODUR ER**. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

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

Some people may get other side effects while taking **FELODUR ER**.

After using it

Storage

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

If you take **FELODUR 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.

Do not store it or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Do not leave it in the car on hot days.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What FELODUR ER looks like

FELODUR ER tablets are available in 3 strengths:

- **FELODUR ER 2.5 mg tablet** - round, yellow, marked "A" over "FL" on one side and "2.5" on the other
- **FELODUR ER 5 mg tablet** - round, pink, marked "A" over "Fm" on one side and "5" on the other
- **FELODUR ER 10 mg tablet** - round, reddish-brown, marked "A" over "FE" on one side and "10" on the other.

All strengths are available in blister packs of 30 tablets.

Ingredients

FELODUR ER tablets contain felodipine 2.5mg, 5mg or 10mg as the active ingredient, plus
Hydrogenated castor oil
Propyl gallate (E 310)
Hypromellose
Sodium aluminium silicate
Cellulose microcrystalline (E 460)
Lactose anhydrous
Sodium stearyl fumarate
Hydroxypropyl cellulose

The coating on each tablet contains
Macrogol 6000
Titanium dioxide (E 171)
Iron oxide yellow (E 172)
Iron oxide red (E 172) (not in 2.5mg tablet)
Carnauba wax (E 903).

Sponsor

AstraZeneca Pty Ltd
ABN 54 009 682 311
Alma Road
NORTH RYDE NSW 2113

Australian Registration Number:
FELODUR ER
2.5mg 60980
5mg 60981
10mg 60982

This leaflet was prepared in May 2009.

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