

FELO ER

Felodipine 5mg & 10mg Extended Release (ER) Tablets



What is in this leaflet

This leaflet answers some common questions about Felo ER. It does not contain all the information available on this medicine. 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 using Felo ER against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet. You may want to read it again.

What Felo ER is used for and how it works

Your Felo ER tablets contain felodipine. It belongs to a group of medicines known as calcium channel blockers.

Felo ER is used to treat high blood pressure (hypertension) and heart and chest pain brought on, for example, by exercise or stress (known as angina pectoris). It works by dilating (expanding) small blood vessels, so that blood can be pumped around the body more easily. It has no negative affect on heart function.

Your doctor may, however, prescribe Felo ER for another reason. Ask your doctor if you have any questions about why Felo ER has been prescribed for you.

Felo ER is only available on prescription from your doctor.

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

Before you take Felo ER

When you must not take it

Do not take Felo ER if:

- **You are allergic to felodipine or any other ingredients listed at the end of this leaflet**
- **You have heart problems (ie. uncompensated heart failure, acute heart attack)**
- **You have angina (chest pain) which has lasted without interruption for 15 minutes or longer and is more severe than usual**
- **You are pregnant**

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.

Talk to your doctor or pharmacist if you are not sure whether you should take this medicine.

Before you take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have any other health problems, including liver or kidney problems.

Tell your doctor or pharmacist if you are pregnant, plan to become pregnant, or are breastfeeding.

Taking other medicines

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

Medicines that may interfere with Felo ER include:

- **Certain anti-ulcer medicines** (cimetidine)
- **Antibiotics** (erythromycin)
- **Anti-fungals** (itraconazole, ketoconazole)
- **Sleeping pills** (barbiturates)
- **Medicine for tuberculosis** (rifampicin)
- **Medicines used to prevent epilepsy** (phenytoin, carbamazepine)
- **Medicines used to prevent the body from rejecting a transplanted organ** (tacrolimus).

These medicines may be affected by Felo ER 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 or pharmacist has more information on medicines to be careful with or avoid while taking Felo ER.

If you drink grapefruit juice, tell your doctor or pharmacist before taking Felo ER.

How to take Felo ER

Directions for use

Felo ER tablets should be taken in the morning. The tablet(s) should be swallowed whole with a glass of water. **Do not divide, crush or chew the tablets.**

Felo ER tablets can be taken without food or following a light meal (not rich in fat or carbohydrate). Do not take Felo ER tablets with grapefruit juice. Grapefruit juice, but not other fruit juices, may increase the effect of Felo ER.

Felo ER is not recommended for use in children.

Hypertension

The usual starting dose is 5mg once daily. If necessary your doctor may increase the dose or add another blood-pressure lowering medicine. The usual dose, when treating this disease for a long time, is 5 to 10mg once daily. In elderly patients, a starting dose of 2.5mg daily may be used.

Angina

The usual starting dose is 5mg once daily and, if needed, your doctor may increase the dose to 10mg once daily. In elderly patients, the starting dose is 5mg daily. If this dose is not effective, your doctor may use an alternative treatment.

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.

If you forget a dose

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.

Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Felo ER

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking Felo ER.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking Felo ER. However, if you become pregnant while taking Felo ER, tell your doctor immediately.

Do not stop taking Felo ER or lower the dose without first checking with your doctor.

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

Do not use Felo ER to treat any other medical complaints, unless your doctor tells you to.

Felo ER is not likely to affect the ability to drive or use machines. However, be careful when driving or operating machinery until you know how Felo ER affects you. When you start taking Felo 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 taking Felo ER.

Side effects

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

All medicines can have some unwanted 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.

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

- Headache
- Dizziness
- Flushing
- Palpitations (rapid heart beat)
- Ankle swelling
- Fatigue (tiredness)

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. However, if they persist, tell your doctor.

A mild enlargement of the gums has been reported in patients with an inflammation in the mouth (gingivitis/periodontitis). This can be reversed or avoided with careful dental hygiene.

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

- Skin rash or itching
- Swelling of your face, lips or tongue; difficulty swallowing or breathing; or hives

These side effects are usually rare but can be serious and need urgent medical attention.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

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

In case of overdose

You should only take the number of tablets that you have been told. If you take more than the recommended number of doses of Felo ER, you may suffer from very low blood pressure and sometimes a slow heart rate. Therefore it is very important that you take the number of doses prescribed by your doctor. If you experience symptoms such as feeling faint, light-headedness or dizziness, contact your doctor or pharmacist immediately.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any Felo ER by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of Felo ER with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the pack/blister strip or if the packaging shows signs of tampering.

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

Store your Felo ER tablets in a cool dry place below 25°C. Keep out of reach of children. Avoid exposure to heat, light and moisture.

Do not store Felo ER, or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you to stop taking Felo ER or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product description

What Felo ER tablets look like

Felo ER 5mg tablets are light pink, round tablets, engraved 5 on one side. They are 9mm in diameter.

Felo ER 10mg tablets are reddish brown, round tablets, engraved 10 on one side. They are 9mm in diameter.

Felo ER is available in blister packs of 90 tablets.

Ingredients

Felo ER tablets contain either 5mg or 10mg of the active ingredient, felodipine.

Each tablet also contains lactose, magnesium stearate, microcrystalline cellulose, silicon dioxide, propyl gallate, povidone, hypromellose, purified talc, ferric oxide – yellow and red, titanium dioxide and propylene glycol.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.
Phone: (09) 579 2792

Date of information

2 February 2009
(Based on datasheet 2 February 2009)