

NEW ZEALAND CONSUMER MEDICINE INFORMATION

FELO 5 ER & FELO 10 ER

Felodipine Extended Release Tablets 5 mg and 10 mg



What is in this leaflet

This leaflet answers some common questions about Felo ER.

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 Felo 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 FELO ER is used for

Felo ER contains the active ingredient felodipine. It belongs to a group of medicines called 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

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 have an allergy to:

- any medicine containing felodipine
- any of the ingredients listed at the end of this leaflet.

Some of the 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.

Do not take Felo ER if you have any of these medical conditions:

- heart problems (such as uncompensated heart failure, acute heart attack)
- angina (chest pain) which has lasted without interruption for 15 minutes or longer and is more severe than normal.

It may not be suitable for you to take this medicine if you have any of these conditions.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not give this medicine to a child.

Safety and effectiveness in children have not been established.

Do not take this medicine after the expiry date printed on the

pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Felo ER.

Taking other medicines

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

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

- certain anti-ulcer medicines (cimetidine)
- antibiotics (erythromycin)
- antifungals (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)

Also tell your doctor if you drink grapefruit juice.

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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Felo ER

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ 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

Hypertension

The usual starting dose is 5 mg once a day. If necessary your doctor may increase the dose or add another blood-pressure lowering medicine. The usual dose when treating this condition for a long time is 5 to 10 mg once a day.

Angina

The usual starting dose is 5 mg once a day and, if needed, your doctor may increase the dose to 10 mg once a day.

How to take it

Swallow the tablets whole with a full glass of water. They must not be divided, crushed or chewed.

When to take it

Felo ER should be taken in the morning.

Taking it at the same time each morning will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine with food, or not, but **do not take with grapefruit juice.** Grapefruit juice, but not other fruit

juices, may increase the effect of Felo ER.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you 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 your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Felo ER. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much 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.

While you are taking Felo ER

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not take Felo ER to treat any other complaints unless your doctor tells you to.

Do not give your 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 Felo ER affects you.

When you start taking this medicine, whether changing from another medicine for high blood pressure or not, you may feel dizzy or faint due to the drop in your blood pressure. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, your dizziness and light-headedness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

This medicine helps most people with high blood pressure or angina 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- flushing
- headache
- dizziness
- palpitations (rapid heartbeat)
- ankle swelling
- fatigue (tiredness)
- nausea (feeling sick)
- frequent urination
- impotence / sexual dysfunction
- stomach pain
- pain, swelling or redness in your gums.

The above list are all mild side effects of Felo 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. However, if they persist tell your doctor.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin rash or itching

- swelling of your face, lips or tongue; difficulty swallowing or breathing; hives.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are usually rare.

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

Other side effects not listed above may also occur in some people.

After taking Felo ER

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

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-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

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

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

Felo 5 ER and Felo 10 ER are available in blister packs of 90 tablets.

Ingredients

Felo 5 ER contains 5 mg of felodipine as the active ingredient.

Felo 10 ER contains 10 mg of felodipine as the active ingredient.

Each tablet also contains:

- lactose monohydrate
- magnesium stearate
- silicon dioxide
- microcrystalline cellulose
- povidone
- propyl gallate
- hypromellose
- propylene glycol
- purified talc
- titanium dioxide (E171)
- iron oxide red (E172)
- iron oxide yellow (E172).

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more

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

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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12 July 2018
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