

FELODIL XR

felodipine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FELODIL XR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FELODIL XR against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What FELODIL XR is used for

FELODIL XR is used to treat high blood pressure.

FELODIL XR belongs to a group of medicines called calcium channel blockers. They work by opening up blood vessels in the body to lower blood pressure and improve the supply of blood and oxygen to the heart.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

FELODIL XR is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take FELODIL XR if you are allergic to felodipine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take FELODIL XR if you have any of the following conditions:

- uncompensated heart failure
- acute myocardial infarction
- cardiac valvular obstruction
- dynamic cardiac outflow obstruction
- unstable angina pectoria

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

Do not take FELODIL XR if you are pregnant or plan to become pregnant.

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your baby can take in FELODIL XR 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 of her treatment. Your doctor can discuss the risks and benefits involved.

Do not give FELODIL XR to children.

There is no information on its use in children.

Do not take it if the expiry date (Exp.) printed on the pack has passed.

It may not work as well if you do.

Do not take FELODIL XR if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

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

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

- any heart problems
- liver problems.

If you have not told your doctor about any of the above, tell them before you start taking FELODIL XR.

Taking other medicines

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

Some medicines may be affected by FELODIL XR, or may affect how well it works. These include:

- cimetidine - a medicine used to treat stomach ulcers or heartburn
- medicines used to treat infections such as erythromycin and rifampicin
- treatment with FELODIL XR 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 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

These medicines may be affected by FELODIL XR or may affect the way FELODIL XR 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.

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.

If you have not told your doctor, dentist or pharmacist about any of these things, tell them before you take any FELODIL XR.

How to take it

How much to take

The usual starting dose is 5 mg once daily. Your doctor may increase this dose depending on how you respond to this medicine.

Doses higher than 20 mg a day are not recommended.

If you are taking other medicines that lower blood pressure, your doctor may need to change the dose

of them to obtain the best results for you.

Elderly people over 65 years and those with liver problems may need smaller doses. An alternate brand of felodipine extended release tablets will be required if a 2.5 mg dose is prescribed as FELODIL tablets must not be broken in half.

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

How to take it

Swallow the tablets whole with a glass of liquid. FELODIL XR should not be chewed or broken up.

If you forget to take it

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.

Otherwise, take the missed dose as soon as you remember (if more than 12 hours to the next dose), and then go back to taking your tablets as you would normally.

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

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

How long to take it for

FELODIL XR helps control your condition, but does not cure it. Therefore you must take it every day. Continue taking your tablets for as long as your doctor tells you to.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much FELODIL XR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include feeling dizzy and fainting due to a drop in blood pressure, irregular or rapid heart beats, shortness of breath and even loss of consciousness.

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking FELODIL XR.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking FELODIL XR.

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

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking FELODIL XR.

If you have to have any blood or urine tests, tell your doctor that you are taking FELODIL XR. It may affect the results of some tests.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not use this medicine to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how FELODIL XR affects you.

FELODIL XR may cause dizziness or light-headedness in some patients, especially when they first start taking the medicine. Make sure you know how you react before driving a car, operating machinery, or doing anything else that could be dangerous if you are affected.

Side effects

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

It helps most people with high blood pressure, but it may have unwanted side effects in some people.

All medicines 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
- palpitations
- dizziness or light-headedness
- tiredness
- swelling in the ankles or legs
- flushing
- feeling sick, vomiting
- red or swollen gums

These are the more common side effects of FELODIL XR. They are usually mild and occur at the beginning of treatment or after an increase in the dose.

Other side effects you should tell your doctor about if they worry you include:

- 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

These side effects are usually mild.

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

- swelling of the face, tongue or back of the throat which may cause difficulty in swallowing or breathing
- difficulty breathing
- chest pain.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using it

Storage

Keep your medicine 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.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

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

If you take the tablets out of the box or the blister pack they may not keep well.

Disposal

If your doctor tells you to stop taking FELODIL XR, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

FELODIL XR comes in 2 strengths of tablets:

- FELODIL XR 5 – round, pale pink tablet.
- FELODIL XR 10 - round reddish- brown tablet.

Each blister pack contains 30 tablets.

Ingredients

The active ingredient in FELODIL XR is felodipine.

- each FELODIL XR 5 tablet contains 5 mg of felodipine
- each FELODIL XR 10 tablet contains 10 mg of felodipine

The tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- hypromellose
- povidone
- propyl gallate
- colloidal anhydrous silica
- magnesium stearate
- purified talc
- propylene glycol
- titanium dioxide
- iron oxide red CI77491

- iron oxide yellow CI7492. The tablets are gluten free.

This medicine contains sugars as lactose.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Australian registration numbers:
FELODIL XR 5: AUST R 128793
FELODIL XR 10: AUST R 128795

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