

FELODIL XR

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 FELODIL XR?

FELODIL XR contains the active ingredient Felodipine. FELODIL XR is used to treat high blood pressure.

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

2. What should I know before I use FELODIL XR?

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 FELODIL XR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FELODIL XR 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 FELODIL XR?

- The usual starting dose is 5 mg once daily. Your doctor may increase this dose depending on how you respond to this medicine.
- Swallow the tablets whole with a glass of liquid. FELODIL XR should not be chewed or broken up.

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

5. What should I know while using FELODIL XR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using FELODIL XR• 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 using this medicine suddenly unless you have discussed it with your doctor.• 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.
Driving or using machines	<ul style="list-style-type: none">• 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
Drinking alcohol	<ul style="list-style-type: none">• Be careful drinking alcohol while using the medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C.• Keep the tablets in their blister pack until it is time to take them.

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

6. Are there any side effects?

All medicines have side effects. Sometimes they are serious, most of the time they are not. Common side effects include- headache, palpitations, dizziness or light-headedness, tiredness, swelling in the ankles or legs, flushing, feeling sick, vomiting, red or swollen gums. You may need medical treatment if you get some of the side effects including- 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.

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.

FELODIL XR

Active ingredient(s): *Felodipine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FELODIL XR. **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 FELODIL XR.**

Where to find information in this leaflet:

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

1. Why am I using FELODIL XR?

FELODIL XR contains the active ingredient Felodipine. FELODIL XR belongs to a group of medicines called calcium channel blockers.

FELODIL XR is used to treat high blood pressure.

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.

2. What should I know before I use FELODIL XR?

Warnings

Do not use FELODIL XR 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.
- 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.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives. take any medicines for any other condition.
- if you have, or have had, any medical conditions, especially the following: any heart problems, liver problems.
- doctor if you are taking any other medicines for any other condition.

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

Check with your doctor if you are pregnant or intend to become pregnant. This medicine may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend 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.

Use in children

- Do not give FELODIL XR to children.
- There is no information on its use in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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.

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

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 FELODIL XR?

How much to take / use

- 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.

When to take / use FELODIL XR

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

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 forget to use FELODIL XR

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

If you use too much FELODIL XR

If you think that you have used too much FELODIL XR, 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.

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.

5. What should I know while using FELODIL XR?

Things you should 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 should not do

- Do not stop using this medicine suddenly unless you discuss with your doctor.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

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.
- 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.

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.

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• palpitations• dizziness or light-headedness• tiredness• swelling in the ankles or legs• flushing• feeling sick, vomiting• red or swollen gums	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>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.</p>
<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> <p>These side effects usually mild</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">swelling of the face, tongue or back of the throat which may cause difficulty in swallowing or breathingdifficulty breathingchest pain.	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.

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 FELODIL XR contains

Active ingredient (main ingredient)	Felodipine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">lactose monohydratemicrocrystalline cellulosehypromellosepovidonepropyl gallatecolloidal anhydrous silicamagnesium stearatepurified talcpropylene glycoltitanium dioxideiron oxide red CI77491

	<ul style="list-style-type: none">iron oxide yellow CI7492.
Potential allergens	The tablets are gluten free. This medicine contains sugars as lactose.

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

What FELODIL XR looks like

- FELODIL XR 5 is round, pale pink tablet (Aust R 128793).
- FELODIL XR 10 is round reddish-brown tablet (Aust R 128795).

Each blister pack contains 30 tablets.

Who distributes FELODIL XR

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

www.arrotex.com.au

This leaflet was prepared in September 2023.