

FENDEX® ER

contains the active ingredient felodipine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FENDEX 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 benefits and risks. Your doctor has weighed the risks of you taking FENDEX ER against the benefits expected 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 FENDEX ER is used for

FENDEX 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 FENDEX ER and told you what dose to take.

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

FENDEX 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.

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 not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

Before you take FENDEX ER

When you must not take it

Do not take FENDEX ER if you have an allergy to:

- any medicine containing felodipine
- any of the ingredients listed at the end of this leaflet
- any other medicine used to treat high blood pressure

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 this medicine if you are pregnant unless advise otherwise by your doctor.

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

Do not take this medicine if you are breastfeeding unless advise otherwise by your doctor. Ask your doctor about the risks and benefits involved.

The active ingredient in FENDEX ER passes into breast milk and there is a possibility that your baby may be affected. However, it is unlikely that amount available to the baby will do any harm.

Do not give this medicine to children.

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 have or have had any of the following medical conditions:

- any heart problem, including angina

It may not be safe for you to take FENDEX ER if you have such condition.

If you have not told your doctor about any of the above, tell him/her before you start taking FENDEX 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 a pharmacy, supermarket or health food shop.

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

- cimetidine, a medicine used to treat stomach ulcers or heartburn
- erythromycin, an antibiotic to treat certain types of bacterial infection
- treatment with FENDEX 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.

These medicines may be affected by FENDEX 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 FENDEX ER

Follow all directions given to you by your doctor and 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

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 5mg tablet taken once daily.

Your doctor will check your progress and if it is needed, increase your dose of FENDEX 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.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush or chew the tablets.

If they are broken or crushed they will not work over 24 hours as they are supposed to.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day 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.

Do not take this medicine with grapefruit juice.

Grapefruit juice, but not other fruit juices, may increase the effect of FENDEX ER.

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 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.

Do not take a double dose to make up for the dose 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 Poisons Information Centre (telephone 13 11 26) 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 FENDEX ER. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include headache, nausea, dizziness and tiredness.

While you are taking FENDEX 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 FENDEX ER.

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

Do not take FENDEX ER with grapefruit juice.

Grapefruit juice, but not other fruit juices, may increase the effect of FENDEX ER.

Things you must not do

Do not take FENDEX 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 change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how FENDEX ER affects you.

When you start taking FENDEX 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 this medicine.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

This medicine helps most people with hypertension, but it may have unwanted side effects in some 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 list 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:

- 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

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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 or go to casualty at your hospital as soon as possible if you notice any of the following:

- skin rash

This can be a serious side effect that may require medical attention. Serious side are rare

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

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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very 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 FENDEX 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 FENDEX ER or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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

- FENDEX ER 2.5 mg: A white, film-coated, round, biconvex, beveled edge tablet debossed with M on one side of the tablet and F2 on the other side. Available in blister packs of 30 tablets.
- FENDEX ER 5 mg: An orange, film-coated, round, biconvex, beveled edge tablet debossed with M on one side of the tablet and F5 on the other side. Available in blister packs of 30 tablets.
- FENDEX ER 10 mg: A beige, film-coated, round, biconvex, beveled edge tablet debossed with M on one side of the tablet and F10 on the other side. Available in blister packs of 30 tablets.

Ingredients

FENDEX ER contains 2.5mg, 5mg or 10mg of felodipine as the active ingredient.

It also contains the following inactive ingredients:

- macrogol 400
- povidone (K29-32)
- butylated hydroxytoluene
- butylated hydroxyanisole
- isopropyl alcohol
- cellulose - microcrystalline
- hypromellose 2208
- silica - colloidal anhydrous
- sodium stearyl fumarate
- Opadry II Complete Film-coating System 40C18303 White (ARTG 13191) (FENDEX ER 2.5 mg only)
- Opadry II Complete Film-Coating System 40C13396 Orange (ARTG 107479) (FENDEX ER 5 mg only)
- Opadry II Complete Film-Coating System 40C97483 Beige (ARTG 107480) (FENDEX ER 10 mg only)
- Opadry II Complete Film-Coating System YS-1-7006 Clear (ARTG 12789).

This medicine does not contain lactose, sucrose, gluten or tartrazine.

Supplier

FENDEX ER is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

- FENDEX ER 2.5 mg: AUST R 184623
- FENDEX ER 5 mg: AUST R 184621
- FENDEX ER 10 mg: AUST R 184622

This leaflet was prepared on 10 October 2012.