

Plendil[®] ER

Felodipine 2.5 mg, 5 mg and 10 mg Extended Release (ER) Tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Plendil ER**. It does not contain all the information that is known about **Plendil ER**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Plendil 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 Plendil ER is used for

Plendil 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).

Plendil ER contains felodipine which belongs to a family of medicines called calcium channel blockers. These medicines do not change the way that the body takes in calcium from food.

Plendil ER 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.

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

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

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

Plendil ER is not addictive.

Before you use Plendil ER

When you must not use it

If you are allergic to any of its ingredients (listed at the end of this leaflet). Inform your doctor if you have had any unusual reactions to other medicines. Some symptoms of an allergic reaction may include, a skin rash, itching or hives, tightness of the chest, wheezing, coughing or difficulty breathing; swelling of the face lips, tongue or other parts of the body.

If you have any of these medical conditions:

- heart problems (i.e. uncompensated heart failure, acute heart attack, cardiac valvular obstruction, dynamic cardiac outflow obstruction)
- angina which has lasted without interruption for 15 minutes or longer and is more severe than usual.

It may not be suitable for you to take **Plendil ER** if you have any of these conditions

Do not use Plendil ER if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Plendil ER should not be used during pregnancy unless your doctor thinks that it is the best medicine for you. It may affect your baby if you take it during pregnancy. You should tell your doctor as soon as possible if you become pregnant.

Tell your doctor if you are breast-feeding or intend to breast-feed before you take Plendil ER. Your baby can take in very small amounts of **Plendil ER** from breast milk if you are breastfeeding, but it is unlikely to affect the baby when the mother is taking doses within normal range for her treatment. Your doctor can explain the risks and benefits involved.

Do not give Plendil ER to children. Plendil is not recommended for use in children.

Do not use after the use by (expiry) date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Plendil ER if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

Before you start to use it

Plendil ER, like other blood-pressure medicines, may in rare cases lead to pronounced low blood pressure. In some patients this may result in an inadequate supply of blood to the heart.

Tell your doctor about any health problems you have had in the past including any allergic, unpleasant or unusual reaction to **Plendil ER** or any other medicine or substance.

This medicine contains lactose. Tell your doctor if you have an intolerance to some sugars.

If you have not told your doctor about any of these things or are unsure about them, tell your doctor or pharmacist before you start taking **Plendil ER**.

Taking other medicines

Tell your doctor if you are taking any other medicines, as treatment with Plendil ER may be influenced if taken at the same time as:

- certain anti-ulcer medicines (cimetidine)
- antibiotics (erythromycin)
- anti-fungals (itraconazole, ketoconazole)
- sleeping pills (barbiturates)
- medicines for infections (such as erythromycin, rifampicin)
- medicines used to prevent epilepsy (phenytoin, carbamazepine)
- medicines used to prevent the body from rejecting a transplanted organ (tacrolimus)
- St John's Wort – a herbal remedy used to treat mood disorders

Certain other medicines or alcohol or food may affect the way **Plendil ER** works. Tell your doctor about any other medicines you are taking including herbal remedies or any medicines you buy or use without a prescription.

Also tell your doctor if you drink grapefruit juice.

Include all medicines that you buy at the chemist, super-market or health food shop. These medicines may affect the way Plendil ER works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you take any Plendil ER.

How to use Plendil ER

How to take it

Swallow Plendil ER tablets whole and wash them down with a glass of water. They must not be divided, crushed or chewed. If they are broken or crushed they will not work over 24 hours as they are supposed to.

It doesn't matter if you take Plendil ER with food or not, but you must not take it with grapefruit juice. Grapefruit juice, but not other fruit juices, may increase the effect of **Plendil ER**.

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 disease for a long time, is 5-10 mg once a day. In elderly patients, a starting dose of 2.5 mg daily may be used.

Stable 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.

When to take it

Plendil ER should be taken in the morning. If you have to take more than one tablet, you must take them together.

How long to take it

Take **Plendil ER** for as long as your doctor tells you to. **Plendil ER** helps control your high blood pressure, but does not cure it. Treatment of high blood pressure or angina 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. 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. Do not take a double dose to make up for the dose that you missed. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are using Plendil ER

Things you must not do

Do not stop taking Plendil ER unless you have discussed it with your doctor. Do not take Plendil ER with grapefruit juice.

Things to be careful of

Be careful driving or operating machinery until you know how Plendil ER affects you. When you start taking **Plendil 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 using Plendil ER.

Overdose

Telephone your doctor or the National Poisons Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Plendil ER. Even if there are no signs of discomfort or poisoning.

If you take more than the recommended number of doses of **Plendil 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Plendil ER. All medicines can 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.

Be sure to tell your doctor if any of the following side effects bother you or continue:

- headache
- dizziness
- flushing
- palpitations (rapid heart beat)
- ankle swelling

These side effects 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.

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

- fatigue (tiredness)
- nausea (feeling sick), vomiting
- fever
- frequent urination
- impotence / sexual dysfunction
- stomach pain
- pain, swelling or redness in your gums.
- 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.

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.

Tell your doctor immediately if you experience:

- Skin rash or itching
- Fainting
- Chest pain
- Rapid heart beat
- Hives, swelling of the face, tongue or throat, as this could indicate a serious allergic reaction.

These are serious side effects. You may need urgent medical attention.

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

Some people may get other side effects while taking **Plendil ER**.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Plendil ER**.

After taking Plendil

Storage

Keep your tablets in the blister pack until it is time to take them. If you take **Plendil ER** out of the blister pack it will not keep well. **Keep it in a cool dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.** Heat and dampness can destroy some medicines. **Do not leave it in the car on hot days.**

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.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What Plendil ER looks like

Plendil ER 2.5 mg are yellow, circular tablets engraved A/FL on one side and 2.5 on the other. They are 8.5 mm in diameter.

Plendil ER 5 mg are pink, circular tablets engraved A/Fm on one side and 5 on the other. They are 9 mm in diameter.

Plendil ER 10 mg are red-brown, circular tablets engraved A/FE on one side and 10 on the other. They are 9 mm in diameter.

Plendil ER is available in blister packs of 30 tablets.

Ingredients

Plendil ER tablets contain felodipine 2.5 mg, 5 mg or 10 mg as the active ingredient, plus

- Hydrogenated castor oil
- Propyl gallate
- Hypromellose
- Sodium aluminium silicate
- Microcrystalline cellulose
- Lactose anhydrous
- Sodium stearyl fumarate
- Hydroxypropyl cellulose

The coating on each tablet contains

- Macrogol 6000
- Titanium dioxide
- Iron oxide yellow
- Iron oxide red (5 and 10 mg only)
- Carnauba wax.

Marketed by:

AstraZeneca Limited
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