

Plendil® 5mg Prolonged-release Tablets

(felodipine)

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.

- * Keep this leaflet. You may need to read it again.
- * If you have any further questions, ask your doctor or pharmacist.
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1 What Plendil is and what it is used for
- 2 Before you take Plendil
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- 5 How to store Plendil
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1 What Plendil is and what it is used for

Plendil contains a medicine called felodipine. This belongs to a group of medicines called "calcium channel blockers". Plendil is used to treat high blood pressure (hypertension). It works by making your blood vessels relax and widen. This helps to lower your blood pressure.

2 Before you take Plendil

Do not take Plendil if:

- * You are allergic (hypersensitive) to felodipine or any of the other ingredients in Plendil tablets (see Section 6: Further information).
- * You are allergic to dihydropyridine medicines (such as nifedipine or amlodipine).
- * You have something called unstable angina (angina that is not well controlled by medical treatment).
- * You have severe heart problems.
- * You have had a heart attack in the last month.
- * You have something called cardiogenic shock (a serious condition where the heart is unable to supply enough blood to the body).
- * You have a disease of the cardiac valves or cardiac muscle (hypertrophic cardiomyopathy).
- * You are pregnant or trying to get pregnant (see "Pregnancy and breast-feeding" below).

Do not take Plendil if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Plendil.

Take special care with Plendil

Before you take Plendil, tell your doctor if:

- * You have liver problems.
- * You have heart problems (i.e. faster heart beats, high and/or low blood pressure).

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes herbal medicines and medicines that you buy without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- * Cimetidine (for ulcers).
- * Erythromycin (for bacterial infections).
- * Itraconazole or ketoconazole (for fungal infections).
- * HIV protease inhibitors (such as ritonavir).
- * Phenytoin, carbamazepine or phenobarbital (for epilepsy).
- * Tacrolimus (used after kidney or liver transplant).
- * Rifampicin (used for treatment of tuberculosis).

- * St John's Wort (Hypericum perforatum) (used to treat depression and anxiety).
- * Barbiturates (a sedative).
- * Efavirenz or Nevirapine (used to treat HIV).
- * Warfarin (used to thin the blood).
- * Ciclosporin (mainly used by transplant patients but also used to treat rheumatoid arthritis and psoriasis).

Taking Plendil with food and drink

Do not drink grapefruit juice while you are taking Plendil tablets. It can affect the way the medicine works.

Pregnancy and breast-feeding

- * Do not take Plendil if you are pregnant or trying to get pregnant. This is because Plendil can harm your unborn baby.
- * If you are breast-feeding, talk to your doctor before using Plendil.

Driving and using machines

If you feel dizzy after taking this medicine, do not drive or use any tools or machines.

Important information about some of the ingredients of Plendil

- * Plendil contains castor oil. This may cause stomach upset and diarrhoea.
- * Plendil contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3 How to take Plendil

Always take Plendil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- * Swallow your tablet(s) whole with a drink of water. Do not divide, crush or chew the tablets.
- * Tablet(s) can be taken without food or following a light meal not high in fat or carbohydrates (sugar).
- * Your tablets are in a pack with the days of the week shown. This will help you to remember when to take them.

Adults with high blood pressure (hypertension)

- * The usual dose is one 5 mg tablet in the morning.
- * However, your doctor may start you on one 2.5 mg tablet.
- * Your doctor may increase the dose to 10 mg.

The Elderly (over 65 years)

- * The usual dose is one 2.5 mg tablet in the morning.
- * In the elderly, the lowest available dose should be used for initial treatment.

Children (under 18 years)

- * There is limited experience with the use of Plendil in children (below the age of 18 years). Therefore Plendil should not be given to children.

People with liver problems

- * If you suffer from liver problems your doctor may give you a lower dose of Plendil.

If you take more Plendil than you should

If you have taken more Plendil than prescribed by your doctor, tell your doctor or go to the nearest hospital straight away. Take the Plendil medicine with you.

If you forget to take Plendil

- * If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- * Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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(felodipine)

Patient Information Leaflet (continued)

4 Possible side effects

Like all medicines, Plendil can cause side effects, although not everybody gets them.

If any of the following happen to you, stop taking Plendil and tell a doctor straight away:

- * Chest pain and dizziness at the same time.
- * An allergic reaction. The signs may include raised lumps on your skin (weals) or swelling of your face, lips, mouth, tongue or throat.

Other possible side effects:

Very common (affect more than 1 in 10 people)

- * Swelling of the feet and ankles.

Common (affects less than 1 in 10 people)

- * Headaches.
- * Flushing of your skin.

Uncommon (affects less than 1 in 100 people)

- * Faster heartbeat.
- * Pounding heartbeat (palpitations)
- * Pins and needles feeling in your toes or fingers.
- * Stomach pain.
- * Feeling sick (nausea).
- * Rash.
- * Itching.
- * Dizziness.
- * Feeling tired.
- * Low blood pressure. This may make you feel faint or dizzy.

Rare (affects less than 1 in 1,000 people)

- * Fainting.
- * Being sick.
- * Pain in joints.
- * Pain in muscles.
- * Being unable to get an erection (impotence).
- * Lumpy rash (hives).

Very rare (affects less than 1 in 10,000 people)

- * Enlarged gums (if you already have enlarged gums they may get worse. You can prevent this by careful dental hygiene).
- * Increased levels of liver enzymes.
- * Skin inflammation.
- * Sensitivity to sunlight.
- * Passing water (urine) more often, normally during the daytime.
- * Allergic reaction (anaphylaxis i.e. swelling of your face, lips, mouth, tongue or throat, fever).

You may get any of the following side effects at the beginning of treatment or if your dose has been increased:

- * Flushing, headaches, faster or pounding heartbeat, feeling dizzy or tired.

Do not be alarmed by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5 How to store Plendil

- * Keep out of the reach and sight of children.
- * Do not use this medicine after the expiry date (EXP) which is stated on the blister strip and the carton. The expiry date refers to the last day of that month.
- * Do not store this medicine above 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Plendil contains

- * The active ingredient is felodipine. Plendil tablets contain 5 mg of felodipine.
- * The other ingredients are Polyoxyl 40 hydrogenated castor oil, hypromellose, propyl gallate, hypromellose, sodium aluminium silicate, microcrystalline cellulose, lactose anhydrous, sodium stearyl fumarate, macrogol, titanium dioxide (E171), iron oxide yellow (E172) and carnauba wax.

What Plendil looks like and contents of the pack

Plendil 5 mg tablets are pink marked with A/FM on one side and 5 on the other side.

Plendil tablets come in blister strips containing 14 tablets which have the days of the week shown. A single pack contains 28 tablets as multiples of the 14 tablet blister strip.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

AstraZeneca AB, Sweden

Pendil is a registered trademark of AstraZeneca AB.

POM PPA 1562/157/001

Revision date: 09/03/2015

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Ltd, Tel: +44 (0) 1527 505414 for help.