Package Leaflet: Information for the Patient

Plendil® 5 mg prolonged-release tablets

Plendil® 10 mg prolonged-release tablets

felodipine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Plendil is and what it is used for

Plendil contains the active substance felodipine. This belongs to a group of medicines called calcium antagonists. It lowers blood pressure by dilating small blood vessels. It does not negatively affect the heart function.

Plendil is used in the treatment of high blood pressure (hypertension) and heart and chest pain brought on by for example exercise and stress (angina pectoris).

2. What you need to know before you take Plendil

Do not take Plendil:
- If you are pregnant. You should tell your doctor as soon as possible if you become pregnant while using this medicine.
- If you are allergic to felodipine or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from uncompensated heart failure.
- If you have acute myocardial infarction (heart attack)
- If you have chest pain of recent onset, or angina pectoris that is lasting for more than 15 minutes or longer or is more severe than usual.
- If you have disease of a heart valve or heart muscle, until you have talked to your doctor.

Warnings and precautions
Plendil, like other blood-pressure lowering medicinal products, may in rare cases lead to pronounced low blood pressure which in some patients may result in an inadequate supply of blood to the heart. Symptoms of excessive low blood pressure and inadequate blood supply to the heart itself, frequently include dizziness and chest pain. If you experience these symptoms, seek emergency care immediately.

Talk to your doctor before taking Plendil, especially if you have problems with your liver.

Taking Plendil may cause your gums to become swollen. Practice good oral hygiene to help avoid your gums from swelling (see section 4).

Children
The use of Plendil is not recommended in children.

Other medicines and Plendil
Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines/herbal remedies can affect treatment with Plendil. Examples are:
- Cimetidine (medicine to treat gastric ulcers).
- Erythromycin (medicine to treat infections).
- Itraconazole (medicine to treat fungi).
- Ketoconazole (medicine to treat fungi)
- Medicines to treat HIV protease inhibitors (such as ritonavir).
- Medicines to treat HIV infection (such as efavirenz, nevirapine)
- Phenytoin (medicine to treat epilepsy).
- Carbamazepine (medicine to treat epilepsy).
- Rifampicin (medicine to treat infections).
- Barbiturates (medicine to treat anxiety, sleeping problems and epilepsy).
- Tacrolimus (medicine used in organ transplantations)

Medicines containing St. John's wort (*Hypericum perforatum)* (herbal product used to treat depression) may reduce the effect of Plendil and should therefore be avoided.

Plendil with food and drink
Do not drink grapefruit juice if you are treated with Plendil, as this may increase the effect of Plendil and the risk of side-effects.

Pregnancy and breast-feeding
Pregnancy
Do not use Plendil if you are pregnant.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Plendil is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Driving and using machines
Plendil can have minor or moderate influence on your ability to drive and use machines. If you experience headache, nausea, dizziness or fatigue your ability to react may be impaired. Caution is recommended especially at the start of treatment.

Plendil contains lactose and macrogolglycerol hydroxystearate (also known as polyoxyl 40 hydrogenated castor oil).

Plendil contains lactose that is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Plendil contains macrogolglycerol hydroxystearate (also known as polyoxyl 40 hydrogenated castor oil), which may cause stomach upset and diarrhoea.

3. How to take Plendil

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
Plendil extended release tablets should be taken in the morning and be swallowed with water. The tablet must not be divided, crushed or chewed. This medicine can be taken without food or following a light meal not high in fat or carbohydrates.

Hypertension
Treatment should be started with 5mg 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 considered.

Stable angina pectoris
Treatment should be started with 5 mg once a day and if needed, your doctor may increase the dose to 10 mg once a day.

If you have liver problems
The level of felodipine in your blood may be increased. Your doctor may lower the dose.

Elderly people
Your doctor may initiate treatment with the lowest available dose.

If you take more Plendil than you should
If you take more than the recommended number of doses of Plendil, you may suffer from very low blood pressure and sometimes palpitations, high or, rarely, 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 immediately.

If you forget to take Plendil
If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Plendil
If you stop taking this medicine your condition may return. Please consult your doctor and seek advice before you stop taking Plendil. Your doctor will advise you how long to take your medicine.

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

4. Possible side effects

Like all medicines, this medicine 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:

- Hypersensitivity and allergic reactions: The signs may include raised lumps on your skin (weals) or swelling of your face, lips, mouth, tongue or throat.

The following undesirable effects have been identified. Most of these reactions appear at start of treatment or after a dose increase. Should such reactions occur, they are usually brief and diminish in intensity with time. If you experience any of the following symptoms and they persist, please tell your doctor.

Mild enlargement of the gums has been reported in patients with an inflammation in the mouth (gingivitis/periodontitis). The enlargement can be avoided or reversed by careful oral hygiene.

Very common: may affect more than 1 in 10 people

- Ankle swelling

Common: may affect up to 1 in 10 people

- Headache
- Flushing

Uncommon: may affect up to 1 in 100 people

- Abnormally rapid heart rate
- Palpitations
- Too low blood pressure (hypotension)
- Nausea
- Abdominal pain
- Burning/prickling/numbness
- Rash or itching
- Fatigue
- Dizziness

Rare: may affect up to 1 in 1,000 people

- Fainting
- Vomiting
- Nettle rash
- Pain in joints
- Muscular pain
- Impotence/sexual dysfunction.

Very rare: may affect up to 1 in 10,000 people

- Gingivitis (swollen gums)
- Increased liver enzymes
- Skin reactions due to increased sensitivity to sunlight
- Inflammation of small blood vessels of the skin
- A need to pass water frequently
- Hypersensitivity reactions such as fever or swelling of the lips and tongue

Other undesirable effects may occur. If you have any bothersome or unusual reaction while taking Plendil, check with your doctor right away.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Plendil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister strip or bottle and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice the packaging is torn or damaged.

Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Plendil contains

- The active substance is felodipine. Each prolonged-release tablet contains 5 mg or 10 mg felodipine.
- The other ingredients of Plendil 5 mg sourced from Italy are: polyoxyl 40 hydrogenated castor oil, hydroxypropyl cellulose, propyl gallate, hypromellose, aluminium sodium silicate, microcrystalline cellulose, anhydrous lactose, sodium stearyl fumarate, polyethylene glycol 6000, titanium dioxide E171, iron oxide E172, carnauba wax and purified water.
- The other ingredients of Plendil 5 mg and 10 mg sourced from Italy, Poland, Romania and Greece are: hydroxypropyl cellulose, hypromellose 50 mPa·s, hypromellose 10000 mPa·s, lactose anhydrous, macrogolglycerol hydroxystearate, microcrystalline cellulose, propyl gallate, sodium aluminium silicate, sodium stearyl fumarate, carnauba wax, iron oxide reddish-brown (E172), iron oxide yellow (E172), hypromellose 6 mPa·s, macrogol 6000, titanium dioxide (E171).

What Plendil looks like and contents of the pack
Plendil 5 mg prolonged-release tablet is pink, circular, biconvex, engraved A/FM on one side and 5 on the other side.
Plendil 10 mg prolonged-release tablet is reddish-brown, circular, biconvex, engraved A/FE on one side and 10 on the other side, with a diameter of 9mm.

Plendil prolonged-release tablets come in blister packs of 28 tablets containing 14 tablets per strip which have the days of the week shown or in a bottle containing 30 tablets. Not all pack sizes may be marketed.

Manufacturers
AstraZeneca AB, Gärtunavägen S-151 85 Södertälje, Sweden or AstraZeneca GmbH, Tinsdaler Weg 183, 22880 Wedel, Germany or AstraZeneca UK Ltd., Silk Road Business Park, Macclesfield SK10 2NA, United Kingdom or Simesa S.p.A., Palazzo Ferraris, Via Ludovico il Moro 6/C – Basiglio, Italy (5 mg only) or AstraZeneca Dunkerque Production, Astrazeneca Reims Production, Parc industriel de la Pompelle, Chemin de Vrilly, 51100 Reims, France.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Numbers:
Plendil 5 mg Prolonged-release tablets PPA0465/405/001
Plendil 10 mg Prolonged-release tablets PPA0465/405/002

Plendil is a registered trademark of AstraZeneca AB.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden, United Kingdom: Plendil
France: Flodil
Germany: Modip
Portugal: Preslow

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