

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Plendil® 2,5 mg (felodipine 2,5 mg) (Tablet)

Plendil® 5 mg (felodipine 5 mg) (Tablet)

Plendil® 10 mg (felodipine 10 mg) (Tablet)

Read all of this leaflet carefully before you start taking PLENDIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PLENDIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT PLENDIL CONTAINS:

Each 2,5 mg tablet contains felodipine 2,5 mg in an extended release formulation.

Each 5 mg tablet contains felodipine 5 mg in an extended release formulation.

Each 10 mg tablet contains felodipine 10 mg in an extended release formulation.

The other ingredients in PLENDIL are:

Carnauba wax, hydroxypropyl cellulose, hypromellose, iron oxide, lactose anhydrous, microcrystalline cellulose, polyethylene glycol, polyoxyl 40 hydrogenated castor oil, propyl gallate, sodium aluminium silicate, sodium stearyl fumarate and titanium dioxide.

Contains sugar (lactose anhydrous).

2. WHAT PLENDIL IS USED FOR:

PLENDIL belongs to a group of medicines called hypotensive medicines (lowers blood pressure).

PLENDIL is used in the treatment of high blood pressure (hypertension).

3. BEFORE YOU TAKE PLENDIL:

Do not take PLENDIL

- If you are allergic to felodipine or any other ingredients of PLENDIL.
- If you have been told by your doctor that you have cardiogenic shock, acute myocardial infarction, uncompensated heart failure and unstable angina pectoris.
- PLENDIL should not be given to children unless your doctor or other health care professional has told you to do so.

Take special care with PLENDIL

Before taking PLENDIL or during treatment tell your doctor, pharmacist or other health care professional if you:

- Have had any previous heart related condition for which you received treatment.
- Have an increase in chest pain within the first few days of treatment with PLENDIL.
- Feel light-headed and feel like you have low blood pressure (hypotension).

Taking PLENDIL with food and drink

Do not take PLENDIL with grapefruit juice as this affects how PLENDIL works.

Do not take PLENDIL after a meal rich in fats (oily foods) or carbohydrates (starchy foods).

Pregnancy and breast-feeding

PLENDIL should not be given during pregnancy.

Felodipine passes through breast milk but is not likely to affect the infant when the mother is taking doses within the normal range for her treatment.

If you are pregnant or breast-feeding your, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery

PLENDIL may cause occasional dizziness or tiredness, this must be considered if you drive or want to handle machinery.

Important information about some of the ingredients of PLENDIL

This medicine contains lactose and may affect those who have a lactose intolerance.

Taking other medicines with PLENDIL

Treatment with PLENDIL may be influenced if taken at the same time as certain anti-ulcer medicines (cimetidine), antibiotics (erythromycin), antifungals (itraconazole, ketoconazole), sleeping pills (barbiturates) and medicines used to prevent epilepsy (phenytoin, carbamazepine) and medicine used to treat tuberculosis (rifampicin).

Treatment with PLENDIL may effect the level of tacrolimus (a medicine given to prevent the body from rejecting a transplanted organ, e.g. kidney or liver) in your blood.

Always tell your healthcare professional if you are taking any other medicine. (This includes

complementary or traditional medicines.)

4. HOW TO TAKE PLENDIL:

- Always take PLENDIL exactly as your doctor has instructed you. You should check with your doctor, pharmacist or other healthcare professional if you are unsure.
- If you have the impression that the effect of PLENDIL is too strong or too weak, talk to your doctor, pharmacist or other healthcare professional.
- PLENDIL should be taken in the morning, swallowed with water. PLENDIL must not be divided, crushed or chewed.
- Do not share medicines prescribed for you with other persons.
- Take PLENDIL once a day, every day, at about the same time each day.
- Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.
- Follow these instructions unless your doctor gave you different advice.
- Remember to take your medicines.

Adults including the elderly:

The usual starting dose for PLENDIL is 5 mg once a day. Once your high blood pressure is controlled the dose may be adjusted to between 5-10 mg once a day.

For adults including the elderly who have a liver problem the maximum dose that can be taken is 10 mg once a day.

Your doctor may prescribe PLENDIL together with other medicines to treat your high blood pressure.

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 (feeling faint, light headedness or dizziness) and sometimes a slow heart rate. Therefore it is very important that you take the number of doses prescribed by your doctor.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take PLENDIL

Take the next dose as usual.

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

PLENDIL can have side effects. Most of these reactions appear at the start of the treatment or after a dose increase. Should such reactions occur, they are usually brief and diminish in intensity with time.

Not all side effects reported for this medicine are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor if you experience any of the following side effects:

Common side effects (less than 1 per 10 but more than 1 per 100 patients):

- Headache, flushing (redness of skin), swelling in the hands, face or feet and ankles

Uncommon side effects (less than 1 per 100 patients but more than 1 per 1000 patients are likely to have them):

- Abnormally rapid heart rate, palpitations (feeling of heart pounding) hypotension (low blood pressure)
- Dizziness, sensation of numbness or pins and needles
- Nausea, upset stomach with stomach pains
- Rash and itching
- Tiredness

Rare side effects (less than 1 per 1000 patients are likely to have them):

- Feeling faint
- Vomiting
- Muscle pain and pain in the joints
- Loss of sexual ability
- Allergic skin reactions
- Gynaecomastia (breast development in men)

Very rare side effects (less than 1 per 10 000 patients are likely to have them):

- Inflammation of the gums (this can be avoided by careful dental hygiene)
- Increased liver enzymes
- Increased sensitivity to sunlight
- Increase in the need to go to the toilet
- Hypersensitivity reactions such as hives and swelling and skin reactions

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF PLENDIL:

Store at or below 30 °C.

Store all medicines out of reach of children.

Keep the container tightly closed in order to protect from light.

Do not use PLENDIL after the expiry date stated on the container.

Return all unused medicine to your Pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF PLENDIL:

PLENDIL is stored in plastic bottles each containing 30 or 100 tablets.

8. IDENTIFICATION OF PLENDIL:

PLENDIL 2,5 mg Tablets:

Yellow, circular, biconvex, film-coated tablets, engraved F^AL on one side and 2,5 on the other side.

PLENDIL 5 mg Tablets:

Pink, circular, biconvex, film-coated tablets, engraved F^AM on one side and 5 on the other side.

PLENDIL 10 mg Tablets:

Red-brown, circular, biconvex, film-coated tablets, engraved F^AE on one side and 10 on the other side.

9. REGISTRATION NUMBER(S):

PLENDIL 2,5 mg Tablets: 29/7.1/0662

PLENDIL 5 mg Tablets: Y/7.1/294

PLENDIL 10 mg Tablets: Y/7.1/295

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION :

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