

PART III: CONSUMER INFORMATION

Pr Plendil®

felodipine extended release tablets

This leaflet is part III of a three-part "Product Monograph" published when PLENDIL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PLENDIL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

PLENDIL is used to treat hypertension (high blood pressure).

WHAT IT DOES:

PLENDIL contains the ingredient called felodipine. It belongs to the group of drugs called "calcium channel blockers" or "calcium antagonists".

PLENDIL relaxes your blood vessels, which lets your blood flow more easily and helps lower your blood pressure.

PLENDIL is formulated as extended release tablets which control the speed of the drug being delivered to the body and ensure even effects over the day.

WHEN IT SHOULD NOT BE USED:

PLENDIL should not be used if you:

- are allergic to felodipine or any of the nonmedicinal ingredients in PLENDIL tablets.
- have a known allergy to other dihydropyridines (calcium channel blockers).
- are pregnant. You should tell your doctor as soon as possible if you become pregnant while using PLENDIL.
- are breast feeding.
- are age 18 or younger.

WHAT THE MEDICINAL INGREDIENT IS:

Felodipine

WHAT THE NONMEDICINAL INGREDIENTS ARE:

aluminum silicate, carnauba wax, castor oil, hydrogen peroxide, hydroxypropyl cellulose, hydroxypropyl methylcellulose, iron oxide, lactose, microcrystalline cellulose, polyethylene glycol, propyl gallate, sodium stearyl fumarate, titanium dioxide.

WHAT DOSAGE FORMS IT COMES IN:

extended release tablets 2.5 mg, 5 mg and 10 mg felodipine

WARNINGS AND PRECAUTIONS

BEFORE you use PLENDIL talk to your doctor or pharmacist if:

- **you are pregnant or plan to become pregnant.**
- **you are breast feeding.**
- you have or have had heart failure.
- you ever had heart or blood vessel disease.
- you have very low blood pressure.
- you are older than 65 years of age.
- you are allergic to "non-medicinal" substances like food products, preservatives, or dyes, which may be present in PLENDIL tablets (See "WHAT THE NONMEDICINAL INGREDIENTS ARE").
- you have ever had a bad, unusual or allergic reaction to "felodipine".

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

A few patients report mild tenderness or swelling of their gums while taking PLENDIL. This effect can be prevented or reversed with good dental care. Brush your teeth carefully and often with a soft toothbrush, and use dental floss daily. Massaging your gums regularly with a soft toothbrush will also help. If your gums do become tender, red or swollen, be sure to tell your doctor or dentist.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about any medicines you are taking or have recently taken, including prescription medications (the ones your doctor writes for you), and over-the-counter medications like cold or allergy medication, or natural health products (herbal medicines). If you visit more than one doctor make sure that each knows about all the medicines you are taking. Certain medicines or alcohol or food may affect the way PLENDIL works.

Drug-Drug Interactions

Drugs that may interact with PLENDIL include:

- certain anti-ulcer drugs (cimetidine)
- antibiotics (erythromycin, clarithromycin)
- antimycotics (itraconazole, ketoconazole),
- sleeping pills (barbiturates)
- drugs used to prevent epilepsy (phenytoin, carbamazepine)-
- tacrolimus. Treatment with PLENDIL 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.

Drug-Food Interactions

Food that may interact with PLENDIL includes:

- Grapefruit juice may also affect treatment with PLENDIL. Do not eat grapefruit or drink grapefruit juice while on PLENDIL.
- Alcohol

- Food rich in carbohydrate and fat

Drug-Herb Interactions

Herbs that may interact with PLENDIL include:

- St. John's Wort

PROPER USE OF THIS MEDICATION

USUAL DOSE:

Adults

Take PLENDIL exactly as your doctor tells you. Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist. Do not take any PLENDIL if it is not prescribed for you.

- PLENDIL is taken once a day. Even if your doctor has prescribed 2 tablets a day, both should be taken at the same time, unless otherwise indicated.
- Try to take PLENDIL with something you do regularly each day; for example, upon waking or at breakfast. This will help you remember each dose.
- Swallow PLENDIL whole with a glass of water. Do not crush, chew, break or suck on the tablets.
- PLENDIL should not be taken with a meal rich in fat or carbohydrates. Breakfast foods which are rich in fat and/or carbohydrates include bacon, sausage, hash brown potatoes, and sugared cereals. PLENDIL may be taken with a light meal which is low in fat and carbohydrates (i.e. two slices of toast with cheese, cereal with milk, and orange juice).
- Do not transfer PLENDIL to other pill containers. To protect your PLENDIL tablets, keep them in the original Compliance Pack.

Check with your doctor if you want to drink alcohol (including wine with your meals) while you are taking PLENDIL. Drinking alcohol while on PLENDIL may make you feel dizzy than usual. Alcohol may also cause an uncomfortable drop in blood pressure.

Remember, you may not notice any signs of high blood pressure. **Therefore it is important to take PLENDIL even when you feel well.** A constant amount of drug is needed in your body to control your blood pressure. **Do not stop taking PLENDIL on your own.**

How to Use the PLENDIL Compliance Pack

To help you keep track of your doses, PLENDIL comes in a blister pack with days of the week printed on the back of the blister. Start with the tablet that matches the day of the week and continue taking them in order until they are all finished.

There are 14 days of labeled tablets in each blister, with one extra to make 15. All 15 tablets, including the one labeled "Take this tablet last", are exactly the same. Once you have finished the 14 labeled tablets take the one marked "Take this tablet last" before starting your next blister pack.

Remember to get a new prescription from your doctor or a refill from your pharmacy a few days before all your tablets are taken.

OVERDOSE:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you take more than the recommended number of doses of PLENDIL, you may suffer from very low blood pressure and sometimes 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.

MISSED DOSE:

If you miss a dose of PLENDIL and remember within 12 hours, you should take your usual dose as soon as possible. Then go back to your regular schedule. But if it is more than 12 hours when you remember, do not take the missed dose. Just take the next dose on time.

Never take a double dose of PLENDIL to make up for missed tablets. If you are still unsure, check with your doctor or pharmacist to see what you should do.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its effects on controlling blood pressure, PLENDIL, like any medication, may include side effects. Some side effects may occur when PLENDIL is first started or when the dose is increased. These side effects are usually mild and should go away as your body gets used to PLENDIL.

It is important that you keep your doctor informed of all side effects, especially if you experience any of the following for more than a week:

- swelling of the ankles;
- a racing heartbeat;
- flushing or a feeling of warmth;
- headache;
- dizziness;
- unusual tiredness

Medicines affect different people in different ways. Just because side effects have occurred in other patients does not mean you will get them. Discuss how you feel on PLENDIL with your doctor and pharmacist. **Do not stop taking PLENDIL on your own.**

Other side effects have been reported in a few cases. These include too low blood pressure (hypotension) as fainting or dizziness, tingling in the hands, arms, feet or legs, stomach upset, diarrhea, nausea, vomiting, abdominal pain, the need to

urinate frequently, fever, and sexual problems. Again, if any of these effects bother you, be sure to tell your doctor.

You should be certain to contact your doctor immediately if you experience anything unusual.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Rash or itchiness	√		
Uncommon	Increased liver enzymes (symptoms like yellowing of the skin or eyes)		√	
Isolated cases	Allergic reactions (symptoms like swelling of the face, lips, tongue and/or throat; rash or other skin reactions; difficulty breathing)			√

***If you think you have these side effects, it is important that you seek medical advice from your doctor immediately.**

This is not a complete list of side effects. For any unexpected effects while taking PLENDIL, contact your doctor or pharmacist.

HOW TO STORE IT

Although the PLENDIL tablets are protected in a Compliance Pack, it is best to keep the package at normal room temperature (15 - 30°C) and in a dry place. Do not keep PLENDIL in the bathroom.

The Compliance Pack protects each tablet. When you first open the package, if you find any damage to the plastic seal or foil which exposes the tablet, ask your pharmacist to check the package.

Keep PLENDIL out of sight and reach of children.

Do not keep or use PLENDIL after the expiry date indicated on the Compliance Pack. Unused medicines which you know you will no longer need should be carefully discarded. You may wish to seek advice from your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca,

or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1 (800) 668-6000

This leaflet was prepared by:

AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

PLENDIL® and the AstraZeneca logo are registered trademarks of the AstraZeneca group of companies.

©AstraZeneca 2000 - 2014

Last revised: January 15, 2015