Module 1.5.5.2 Patient information leaflet

PATIENT INFORMATION LEAFLET FOR FEDALOC 30 mg / 60 mg SR TABLETS

Please read this leaflet carefully before you start taking FEDALOC tablets.

- Keep this leaflet. You may need to read it again.
- It does not contain all the available information about your medicine.
- If you have further questions, please ask your doctor or your pharmacist.
- **FEDALOC SR** 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.

SCHEDULING STATUS

Schedule 3.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FEDALOC 30 mg SR (slow release film coated tablets)

FEDALOC 60 mg SR (slow release film coated tablets)

1. WHAT FEDALOC SR CONTAINS

Active ingredients:

FEDALOC 30 mg SR: Each slow release tablet contains 30 mg nifedipine.

FEDALOC 60 mg SR: Each slow release tablet contains 60 mg nifedipine.

Inactive ingredients:

Purified talc, povidone, methylene chloride, purified water, lactose monohydrate, hydroxypropylmethylcellulose, carbomer, silica colloidal anhydrous, magnesium stearate.

2. WHAT FEDALOC SR IS USED FOR?

- Treatment of mild to moderate high blood pressure.
- Preventative treatment (prophylaxis) and treatment of chronic stable angina pectoris (type of chest pain).

3. BEFORE YOU TAKE FEDALOC SR

Do not take FEDALOC SR:

- If you are allergic (hypersensitive) to nifedipine or any other (see "**WHAT FEDALOC SR CONTAINS**").
- If you suffer from liver problems.
- If you have low blood pressure (light headedness or dizziness).
- If you have a slow heart rate.
- If you had a heart attack in the last 4 weeks.
- If you have a heart condition called angina (chest pain) which is stable and may lead to a heart attack.
- If you have a blockage in your throat or a narrowing in any part of you digestive system.
- If you are currently experiencing a heart disorder called cardiogenic shock.
- If you have a condition called inflammatory bowel disease.
- If you have a condition called porphyria.
- If you are taking rifampicin (used in the treatment of tuberculosis (TB)).

FEDALOC SR is not recommended for use in children.

Take special care with FEDALOC SR:

- If you have low blood pressure (light headedness or dizziness).
- If you have any other heart disorders.
- If you stop treatment with **FEDALOC SR** suddenly. It may increase the incidence of angina (a heart disorder).
- If you suffer from liver problems.

- If you experience heart pain after taking **FEDALOC SR**. Your doctor may need to stop **FEDALOC SR** treatment.
- Your doctor will need to monitor your blood pressure when you start taking **FEDALOC SR** or when your dose is adjusted.
- **FEDALOC SR** is not a replacement for nitroglycerine tablets, taken under the tongue, in an acute attack of angina (chest pain).
- If you are lactose intolerant (when you are unable to digest lactose, a sugar found in milk).

Taking FEDALOC SR with food or drink:

FEDALOC SR tablets should be swallowed whole with a glass of water. The tablets should not be divided, chewed or crushed.

FEDALOC SR may be taken with or without food.

Grapefruit juice: You should not take grapefruit juice while on treatment with **FEDALOC SR**

Pregnancy and breastfeeding:

Do not take **FEDALOC SR** tablets if you are pregnant, planning to become pregnant or breastfeeding. Please consult your doctor if you suspect you are pregnant.

Driving and using machinery:

FEDALOC SR tablets may cause dizziness or light headedness. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **FEDALOC SR** tablets affect you.

Taking other medicines with FEDALOC SR:

Consult your doctor, pharmacist or healthcare professional for advice if you need to take any other medicines. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **FEDALOC SR** with these medicines may cause undesirable interactions.

Do not use the following medicines in combination with **FEDALOC SR**:

- Digoxin (used in the treatment of heart disorders).
- Phenytoin (used in the treatment of epilepsy or seizures/fits).
- Quinidine (used to treat an irregular heartbeat).
- Quinupristin / dalfopristin (a combination antibiotic for certain types of infections).
- Cimetidine (used to treat stomach ulcers or heartburn).
- Rifampicin (used to treat tuberculosis (TB).
- Diltiazem (used to treat high blood pressure and certain heart disorders).
- Erythromycin (an antibiotic used to treat certain types of infections).
- Fluoxetine (used to treat depression).
- Indinavir, ritonavir, saquinavir (used in the management of HIV).
- Ketoconazole, itraconazole, fluconazole (used to treat fungus infections).
- Carbamazepine (used to treat epilepsy or seizures/fits).
- Tacrolimus (used to suppress the immune system in organ transplants).
- Nefazodone (used to treat depression).
- Phenobarbitone (used to treat epilepsy or seizures/fits).
- Valproic acid (used to treat epilepsy or seizures/fits).

4. HOW TO TAKE FEDALOC SR

FEDALOC SR tablets should be swallowed whole with a glass of fluid.

The tablets should not be divided, chewed or crushed.

The tablets should be taken at approximately 24 hour intervals, i.e. at the same time each day, preferably in the morning.

FEDALOC SR may be taken with or without food.

The recommended dosage is 30 mg (one tablet) once daily.

This dosage may be increased by your doctor to a maximum of 90 mg once daily.

If you are not sure how many tablets to take, ask your doctor or pharmacist.

If you take more FEDALOC SR than you should:

In the event of overdose, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre immediately. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your FEDALOC SR:

If you forget to take your medicine, take the missed dose as soon as you remember.

However, if it is almost time for you next dose, continue to take the next tablet at the usual time.

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

5. POSSIBLE SIDE EFFECTS

FEDALOC SR may cause side effects.

Not all side effects reported for FEDALOC SR is included in this leaflet.

Should your general health worsen while taking FEDALOC SR, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor if any of the following side effects continue or are bothersome which may occur frequently:

- Swelling of the limbs.
- Nausea.
- Headache.

Less frequent side effects that may occur include the following:

- Chest pain.
- Abnormal heartbeat.
- Eye pain, vision disorders.
- Constipation.

- Dizziness, light-headedness.
- Changes in your mood (feeling unhappy).
- Increased frequency of urination.
- Skin rash.
- Fever.
- Exhaustion.

6. STORING AND DISPOSING OF FEDALOC SR

- Store below 25 °C.
- Keep the container tightly closed.
- Keep the blister in the outer carton until required for use.
- Protect from light and moisture.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF FEDALOC SR

White polypropylene securitainers with a white snap-on lid containing 30 or 100 tablets.

Opaque white, PVC/PVDC/ Aluminium foil blisters containing 28 tablets in an outer carton.

Opaque white, PVC/PVDC/ Aluminium foil blisters containing 30 tablets in an outer carton.

8. IDENTIFICATION OF FEDALOC SR

FEDALOC 30 mg SR: Round, biconvex, pale red colour, marked "30" on one side, film coated tablets in a controlled release formulation. Diameter: 7,00 mm.

FEDALOC 60 mg SR: Round, biconvex, pale red colour, marked "60" on one side, film coated tablets in a controlled release formulation. Diameter: 11,00 mm.

9. REGISTRATION NUMBERS

FEDALOC 30 mg SR: 37/7.1/0302

FEDALOC 60 mg SR: 37/7.1/0303

10. NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMA DYNAMICS (PTY) LTD.

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11. DATE OF PUBLICATION

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