PATIENT INFORMATION LEAFLET

FEDALOC SR RANGE

SCHEDULING STATUS

S3

FEDALOC 30 mg SR slow release film coated tablets

FEDALOC 60 mg SR slow release film coated tablets

Nifedipine

Each FEDALOC 30 mg SR film coated tablet contains sugar (lactose monohydrate 15 mg).

Each FEDALOC 60 mg SR film coated tablet contains sugar (lactose monohydrate 30 mg).

Read all of this leaflet carefully before you start taking FEDALOC SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- 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.

What is in this leaflet

1. What FEDALOC SR is and what it is used for

FEDALOC SR belongs to a group of medicines called calcium channel blockers.

FEDALOC SR is used to treat high blood pressure or angina (chest pain).

In patients with high blood pressure, FEDALOC SR relaxes and opens blood vessels improving the flow of blood and lowering blood pressure.

In patients with angina (chest pain), FEDALOC SR works by improving blood supply and oxygen to the heart muscle.

FEDALOC SR may be used alone or in combination with other medicines used to treat high blood pressure and angina.

2. What you need to know before you take FEDALOC SR

Do not take/use FEDALOC SR:

- if you are hypersensitive (allergic) to nifedipine, other dihydropyridines (used to lower blood pressure) or to any of the other ingredients of FEDALOC SR (listed in section 6)
- if you have ever had a collapse caused by a slow heart rate (cardiogenic shock), during which you became breathless, pale and had a cold sweat and dry mouth
- if you suffered a heart attack in the last 4 weeks
- if you suffer from a condition called aortic stenosis with symptoms such as fatigue, feeling faint or fainting when exercising and shortness of breath
- if you have a heart condition called angina (chest pain) which is unstable
- if you suffer from liver problems
- if you have low blood pressure (light headedness or dizziness) or if you experienced a sudden drop in blood pressure
- if you have a slow heart rate or heart failure
- to prevent a heart attack

- if you have a blockage in your throat or a narrowing in any part of you digestive system
- if you have a condition called inflammatory bowel disease (abdominal pain or cramping, diarrhoea, bloody stools, weight loss)
- if you are taking rifampicin (a medicine used in the treatment of tuberculosis)
- if you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility)
- if your blood pressure continues to rise despite treatment (malignant hypertension)
- if you have a “Kock pouch” (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.

Warnings and precautions

Do not break, bite or chew your tablets, FEDLOC SR needs to be swallowed whole.

Take special care with FEDALOC SR:

- if you have low blood pressure (light headedness or dizziness) or other heart conditions including heart failure or you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve)
- during an episode of chest pain if you have already been diagnosed with a heart condition called angina (a type of chest pain) or you have very high blood pressure that needs to be lowered as soon as possible
- if you have been diagnosed with severe aortic stenosis (narrowing of the valve in the large blood vessel branching off the heart (aorta))
- if you are breastfeeding your baby. If you need to take FEDALOC SR, you should stop breastfeeding before you start to take this medicine (see Do not take FEDALOC SR)
- if you suffer from liver problems your dose of FEDLOC SR may need to be adjusted
- if you are taking another heart medicine with FEDLOC SR your doctor will need to monitor your progress
- if you are diabetic FEDLOC SR may affect how your diabetes medicines work and your

normal dose may need to be adjusted

- if you have kidney problems and are on dialysis. If you have a very high blood pressure and a low blood volume, you might experience a sudden drop in blood pressure when you take FEDALOC SR
- if you take medicines such as certain antibiotics, medicine for depression, seizures and quinidine (for treatment of abnormal heart rhythm) (see Other medicines and FEDALOC SR)
- your doctor will need to monitor your blood pressure when you start taking FEDALOC SR, when your dose is adjusted, or if you are also taking other medicines
- FEDALOC SR is not a replacement for nitroglycerine tablets, taken under the tongue, in an acute attack of angina (chest pain)
- if you stop treatment with FEDALOC SR suddenly, as it may increase the incidence of angina (a heart disorder with severe chest pain)
- if you experience heart pain after taking FEDALOC SR. Your doctor may need to stop FEDALOC SR treatment
- if you are to have a barium contrast x-ray (barium meal). These tablets may affect the results of the test
- If you are more than 20 weeks pregnant, as FEDALOC SR may harm your baby (see Pregnancy, breastfeeding and fertility)
- changing the brand of medicine containing nifedipine is not advised
- if you are giving a urine sample. FEDALOC SR may interfere with the results of certain urine tests.

Other medicines and FEDALOC SR

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

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

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

The intake of alcohol whilst taking FEDALOC SR may affect the way FEDALOC SR works. Cigarette smoking has been shown to interfere with the way FEDALOC SR works.

Do not start taking FEDALOC SR within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Also, do not drink grapefruit juice or eat grapefruit whilst taking FEDALOC SR. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

FEDALOC SR with food and drink

You should not take grapefruit juice while on treatment with FEDALOC SR as grapefruit juice may increase the effect of FEDALOC SR (see How to take Fedaloc SR).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Do not take FEDALOC SR tablets if you are pregnant, planning to become pregnant or breastfeeding. If you need to take FEDALOC SR, you should stop breastfeeding before you start taking this medicine.

Driving and using machines

FEDALOC SR tablets may cause dizziness or light headedness. This applies particularly at the start of treatment, on changing the medication and in combination with alcohol. Do not drive, operate machinery, or do anything else that could be dangerous until you know how FEDALOC SR tablets affect you.

It is not always possible to predict to what extent FEDALOC SR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FEDALOC SR affects them.

FEDALOC SR contains lactose monohydrate

FEDALOC SR contains lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take FEDALOC SR.

FEDALOC SR contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take FEDALOC SR

Do not share medicines prescribed for you with any other person. Always use FEDALOC SR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are

not sure.

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

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

Adults:

The usual dose 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.

Your doctor will decide on the dose depending on your condition.

Children:

FEDALOC SR is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

Your doctor will tell you how long your treatment with FEDALOC SR will last. Do not stop treatment early because your high blood pressure may return.

If you have the impression that the effect of FEDALOC SR is too strong or too weak, tell your doctor or pharmacist.

If you take more FEDALOC SR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the

nearest hospital or poison centre.

Symptoms of overdose may include:

- a drop in blood pressure, irregular, slow or fast heartbeat, increased glucose levels in the blood (hyperglycaemia), increased acid levels, fluid build-up in the lungs, flushing, headaches.

If you forget to take FEDALOC SR

If you forget to take FEDALOC SR, take 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 forgotten individual doses.

If you stop taking FEDALOC SR

It is important that you continue the course of treatment even if you begin to feel better after a few days. If your treatment with FEDALOC SR is stopped suddenly, your chest pain may worsen.

4. Possible side effects

FEDALOC SR can have side effects.

Not all side effects reported for FEDALOC SR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using FEDALOC SR, please consult your healthcare provider for advice.

If any of the following happens, stop using FEDALOC SR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FEDALOC SR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- rapid heartbeat (tachycardia), palpitations, chest pain
- low blood pressure (hypotension) with symptoms such as fainting or light-headedness
- swelling in any part of the body
- shortness of breath
- high blood sugar levels (hyperglycaemia)
- hepatitis, a liver condition, with symptoms such as stomach pain, fever, nausea, vomiting or loss of appetite
- jaundice (yellow discolouration of the skin and eyes)
- kidney problems (passing less or more urine than is normal for you or waking up at night to urinate)
- difficulty in swallowing
- severe skin reactions including blistering of the skin, mouth, eyes and genitals, as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, light-headedness

- eye pain
- constipation
- skin conditions such as a rash, excessive skin pigmentation, hives, itchy skin, sensitivity of skin to sunlight, complete or partial hair loss in hairy areas of body
- feeling unwell

Less frequent side effects:

- abnormal blood test results (blood disease or disorder), increased bleeding after surgery
- anxiety or nervousness, sleep disorders, aggression, need to keep moving, pacing, unusually or excessively excitable, depression, mood changes
- dizziness, migraine, reduced sense of touch or sensation (numbness), tingling sensation in hands, feet or lips (feeling of “pins and needles”), involuntary trembling (tremors), sleepiness, lack of energy and enthusiasm, stroke
- blurred vision, worsening eyesight, brief loss of vision, lazy eye
- ringing in the ears (tinnitus), loss of balance (vertigo)
- flushing
- nosebleeds, nasal congestion (stuffy nose) reduced sense of smell
- stomach pain, vomiting, diarrhoea, indigestion, excess gas (wind), nausea, dry mouth, swelling of the gums, heartburn or indigestion (gastroesophageal sphincter insufficiency)
- temporary increase in certain liver enzymes, cholestasis (liver condition) with symptoms such as intense itching
- redness of skin, raised areas of bleeding in the skin (palpable purpura), dilation of small blood vessels, creating small, red markings on the skin (photo-distributed telangiectasias), blistering of the skin (pemigold nodularis)
- joint pain, back pain, muscle cramps or weakness
- problems with sexual performance, breast enlargement in men, painful or abnormal menstruation, breast pain and discomfort

- feeling unwell, general pain, chills.

The following side effects have been reported but the frequency for them to occur is not known:

- severe decrease in a specific class of white blood cell (agranulocytosis), a reduction in the number of white blood cells (leucopenia)
- total or partial loss of sensation in a part of your body (hypoaesthesia)
- difficulty in breathing, swelling in lungs
- stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal, difficulty swallowing, abdominal pain, caused by obstruction of the gut or ulcers in the gut, vomiting, stomach ulcer

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of FEDALOC SR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store FEDALOC SR

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blisters in carton until required for use.

Protect from light and moisture

Do not store in a bathroom

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What FEDALOC SR contains

The active ingredient is nifedipine.

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

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

The other ingredients are:

Tablet cores:

Carbomer, hydroxypropylmethylcellulose, lactose monohydrate, magnesium stearate, povidone K30, silica colloidal anhydrous, talc.

Film coating

Eudragit E, ferric oxide red (77491), hydroxypropylmethylcellulose, macrogol 4000, magnesium stearate, talc, titanium dioxide (77891).

What FEDALOC SR looks like and contents of the pack

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

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

FEDALOC SR tablets are available in:

White polypropylene securitainers with a tear tab cap 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.

Holder of Certificate of Registration

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