PATIENT INFORMATION LEAFLET

FEDALOC RANGE

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

FEDALOC 30 mg SR slow release film coated tablets

FEDALOC 60 mg SR slow release film coated tablets

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 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.

1. WHAT FEDALOC SR CONTAINS:

The active substance in **FEDALOC SR** 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 carbomer, Eudragit E, ferric oxide red (77491), hydroxypropyl methylcellulose, lactose monohydrate, Macrogol 4000, magnesium stearate, povidone, purified talc, silica colloidal anhydrous, titanium dioxide (77891).

FEDALOC SR tablets contain sugar in the form of lactose monohydrate.

2. WHAT FEDALOC SR IS USED FOR:

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

3. BEFORE YOU TAKE FEDALOC SR:

Do not take FEDALOC SR:

- if you are hypersensitive (allergic) to nifedipine, other dihydropyridines (used to lower blood pressure) or any of the other ingredients of **FEDALOC SR** (see **WHAT FEDALOC SR CONTAINS**)
- 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 have a slow heart rate
- 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 suffered a heart attack in the last 4 weeks
- to prevent a heart attack
- if you have a heart condition called angina (chest pain) which is unstable
- 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 blockage in your throat or a narrowing in any part of your 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 AND LACTATION**)
- **FEDALOC SR** is not recommended for use in children.

Take special care with FEDALOC SR:

- during an episode of chest pain if you have already been diagnosed with a heart condition called angina (a type of chest pain)
- changing the brand of medicine containing nifedipine is not advised
- if you are taking another heart medicine with **FEDLOC SR** your doctor will need to monitor your progress
- **FEDALOC SR** is not a replacement for nitroglycerine tablets, taken under the tongue, in an acute attack of angina (chest pain)
- if you have low blood pressure (light headedness or dizziness) or other heart conditions
- 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 suffer from liver problems your dose of **FEDLOC SR** may need to be adjusted
- if you are diabetic **FEDLOC SR** may affect how your diabetes medicines work and your normal dose may need to be adjusted
- 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**, when your dose is adjusted, or if you are also taking other medicines
- if you have kidney problems and are on dialysis
- if you are pregnant or breastfeeding your baby (see **PREGNANCY AND LACTATION** and **DO NOT TAKE FEDALOC SR**)
- if you take medicines such as certain antibiotics, medicine for depression, seizures and quinidine (for treatment of abnormal heart rhythm) (see **Taking other medicines**

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with FEDALOC SR).

Taking FEDALOC SR with food and 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** as grapefruit juice may increase the effect of **FEDALOC SR**.

Pregnancy and breastfeeding:

Do not take **FEDALOC SR** tablets if you are pregnant, planning to become pregnant or breastfeeding. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **FEDALOC SR**.

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.

Important information about some of the ingredients of FEDALOC SR:

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

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

Taking other medicines with FEDALOC SR:

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

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

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

4. HOW TO TAKE FEDALOC SR:

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

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

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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 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.

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 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.

Symptoms of overdose include a drop-in blood pressure, irregular, slow or fast heartbeat, increased glucose levels in the blood (hyperglycemia), increased acid levels, fluid build-up in the lungs.

If you forget to take a dose of 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 the forgotten individual doses.

Effects when treatment with FEDALOC SR is stopped:

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.

5. POSSIBLE SIDE EFFECTS:

FEDALOC SR may 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 taking **FEDALOC SR** please consult your doctor, pharmacist or other healthcare professional for advice.

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

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

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)
- fainting (syncope)
- kidney problems (passing less or more urine than is normal for you or waking up at night to urinate)
- difficulty in swallowing.

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, dizziness, light-headedness
- constipation, nausea
- 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.

Less frequent side effects:

- abnormal blood test results
- cholestasis (liver condition) with symptoms such as intense itching
- increased bleeding after surgery
- joint pain, back pain, muscle cramps or weakness
- migraine
- mood and/or sleep disorders, exhaustion, fatigue
- anxiety, aggression, need to keep moving, pacing, unusually or excessively excitable
- depression
- reduced sense of touch or sensation (numbness)
- tingling sensation in hands, feet or lips (feeling of “pins and needles”)
- involuntary trembling (tremors)

- blurred vision, worsening eyesight, eye pain
- ringing in the ears (tinnitus), loss of balance (vertigo)
- flushing, fever, sweating
- stomach pain, vomiting, diarrhoea, indigestion, excess gas (wind)
- nosebleeds, nasal congestion (stuffy nose) reduced sense of smell
- dry mouth, swelling of the gums
- serious skin conditions causing blisters and peeling
- change in taste perception (including loss of taste)
- problems with sexual performance, breast enlargement in men
- painful or abnormal menstruation, breast pain and discomfort
- feeling unwell, general pain, chills.

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

6. STORING AND DISPOSING OF FEDALOC SR:

Store at or below 25 °C

Keep the container tightly closed

Keep the blister in the outer carton until required for use. Protect from light and moisture

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)

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.