**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S3

**NIFEDALAT 20 SR, film-coated slow-release tablets**

**Nifedipine**

**Contains sugar (lactose 9,8 mg per tablet)**

**Read all of this leaflet carefully before you start taking NIFEDALAT 20 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.
- NIFEDALAT 20 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 NIFEDALAT 20 SR is and what it is used for

NIFEDALAT 20 SR contains the active substance nifedipine, which belongs to a group of medicines called calcium antagonists.

NIFEDALAT 20 SR is used to treat mild to moderate high blood pressure (hypertension) and to prevent the condition

called chronic stable angina pectoris (chest pain coming from the heart) in adults.

## 2. What you need to know before you take NIFEDALAT 20 SR

**Do not take NIFEDALAT 20 SR:**

- if you are hypersensitive (allergic) to nifedipine or any of the other ingredients of NIFEDALAT 20 SR (listed in section 6).
- if you have a liver disease that prevents your liver from working properly.
- if you have an obstruction or narrowing in your intestines, or have had this in the past.
- if you have ever had an obstruction in the gullet (the oesophagus - the tube connecting the throat to the stomach).
- if you have inflammation of the bowel or intestines.
- if you have ever had a collapse caused by a heart problem (cardiogenic shock), during which you became breathless, pale and had a cold sweat and dry mouth.
- if you are pregnant or breastfeeding.
- if you are a child or below the age of 18 years.

**Warnings and precautions**

Take special care with NIFEDALAT 20 SR:

- if you have low blood pressure, or if you are already taking other medicines to treat high blood pressure, and you were prescribed NIFEDALAT 20 SR for your angina. Your blood pressure may be decreased further by this treatment.
- if you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve).
- if you have been told that you have a narrowing of the aortic heart valve (stenosis).
- if your chest pain (angina) gets worse (comes on more often or more severely) over a matter of hours or days. You may be advised not to take NIFEDALAT 20 SR.
- if you have chest pains after taking your first dose of NIFEDALAT 20 SR. Your doctor may wish to change your

treatment.

- if you are a diabetic. The treatment for your diabetes may need to be adjusted. If you have any questions about this, ask your doctor.
- if you are on kidney 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 NIFEDALAT 20 SR.
- if you are giving a urine sample. NIFEDALAT 20 SR may interfere with the results of certain urine tests.
- if you are to have a barium contrast x-ray (barium meal). NIFEDALAT 20 SR may affect the results of the test.
- if you notice increased breathlessness.
- if you notice swelling of the ankles.

**Children and adolescents**

NIFEDALAT 20 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.

**Other medicines and NIFEDALAT 20 SR**

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

Some medicines may affect the way NIFEDALAT 20 SR works. Tell your doctor if you are taking:

- rifampicin (an antibiotic)
- erythromycin (macrolide antibiotics)
- indinavir, nelfinavir, ritonavir, saquinavir or amprenavir (to treat HIV)
- ketoconazole, itraconazole or fluconazole (anti-fungal medicines)
- fluoxetine or nefazodone (to treat depression)
- quinupristin/ dalfopristin (a combination antibiotic)

- phenytoin, carbamazepine or valproic acid (to treat epilepsy)
- phenobarbital (usually used to treat insomnia or anxiety).
- cimetidine (to treat stomach ulcers)
- cisapride (to treat reduced movements of the gullet and stomach).

NIFEDALAT 20 SR may affect the way some other medicines work. Tell your doctor if you are taking:

- other medicines to treat high blood pressure
- digoxin, diltiazem, quinidine or beta-blockers (to treat heart conditions)
- tacrolimus (to prevent the rejection of transplanted organs).

**NIFEDALAT 20 SR with food and drink**

You can take NIFEDALAT 20 SR with or without food.

**Do not drink grapefruit juice or eat grapefruit while taking NIFEDALAT 20 SR**

Do not start taking NIFEDALAT 20 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 NIFEDALAT 20 SR. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

**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 taking this medicine.

NIFEDALAT 20 SR is not recommended for use during pregnancy.

Do not take NIFEDALAT 20 SR if you are breastfeeding. If you need to take NIFEDALAT 20 SR, you should stop breastfeeding before you start taking the tablets.

No fertility studies have been conducted in humans.

**Driving and using machines**

It is not always possible to predict to what extent NIFEDALAT 20 SR may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which NIFEDALAT 20 SR affects you.

NIFEDALAT 20 SR may make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way. This may be more likely when you first start treatment, if you change tablets, or if you have drunk alcohol.

**NIFEDALAT 20 SR contains sugar (lactose)**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NIFEDALAT 20 SR.

## 3. How to take NIFEDALAT 20 SR

Do not share medicines prescribed for you with any other person.

Always take NIFEDALAT 20 SR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 20 mg to 40 mg twice per day.

Swallow the tablets whole. Do not bite, chew or break them.

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

Take the tablets with a glass of fluid. Do not take them with grapefruit juice.

Your doctor will tell you how long your treatment with NIFEDALAT 20 SR will last.

If you have the impression that the effect of NIFEDALAT 20 SR is too strong or too weak, tell your doctor or pharmacist

**Special populations**

*Use in elderly*

No dose adaptation in elderly people above 65 years is necessary.

*Use in adults with kidney problems*

No dosage adjustment is required in patients with kidney problems.

*Use in patients with liver impairment*

NIFEDALAT 20 SR should not be administered to patients with liver impairment (see section 2, 'Do not take NIFEDALAT 20 SR').

*Use in children and adolescents*

NIFERDALAT 20 SR is not recommended for use in children and adolescents below 18 years of age (see section 2, 'Do not take NIFEDALAT 20 SR').

**If you take more NIFEDALAT 20 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.

Taking too many tablets may cause your blood pressure to become too low and your heartbeats to speed up or slow down. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

**If you forget to take NIFEDALAT 20 SR**

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

## 4. Possible side effects

NIFEDALAT 20 SR can have side effects.

Not all side effects reported for NIFEDALAT 20 SR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NIFEDALAT 20 SR, please consult your healthcare provider for advice.

If any of the following happens, stop taking NIFEDALAT 20 SR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe, sudden generalised allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse)
- swelling (including potentially life-threatening swelling of the airway)
- other allergic reactions causing swelling under the skin (possibly severe and including swelling of the larynx that may result in a life-threatening outcome)
- fast heartbeat (tachycardia)
- shortness of breath (frequency not known) or difficulty breathing

- mild to moderate allergic reactions
- itching (possibly severe), a rash or hives
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to NIFEDALAT 20 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:

- a skin reaction or blistering or peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (Toxic Epidermal Necrolysis).

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
- swelling, particularly of the ankles and legs
- flushing
- constipation
- general feeling of being unwell.

*Less frequent side effects:*

- anxiety or nervousness
- sleep disorders
- sensation of spinning or whirling motion (vertigo)
- migraine

- dizziness
- trembling
- pins and needles
- blurred vision
- irregular heartbeat (palpitations)
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- nosebleed
- nasal congestion
- stomach pain (abdominal pain)
- feeling sick (nausea)
- indigestion or upset stomach
- wind (flatulence)
- dry mouth
- inflammation of the gums, tender or swollen gums, bleeding gums
- temporary increase in certain liver enzymes
- reddening of the skin
- muscle cramps
- joint swelling
- increase in the need to pass water (urinate)
- painful or difficult urination
- inability to achieve or maintain an erection (impotence)
- unspecified pain
- chills.

*Frequency not known:*

- a more severe decrease in a specific class of white blood cell (agranulocytosis)
- a reduction in the number of white blood cells (leucopenia)
- increased blood sugar (hyperglycaemia)
- depression
- decreased skin sensitivity (hypoaesthesia)
- drowsiness (somnolence)
- difficulty sleeping (insomnia)
- eye pain
- chest pain (angina pectoris)
- heart attack
- vomiting
- heartburn or indigestion (gastroesophageal sphincter insufficiency)
- yellowing of the whites of the eyes or skin (jaundice)
- sensitivity to light (photosensitivity allergic reaction)
- small, raised areas of bleeding in the skin (palpable purpura)
- joint pain
- muscle pain
- temporary enlargement of male breast tissue
- sweating
- feeling of warmth
- tiredness.

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/documetns/adverse-drug-reactions-and-quality-problem-reporting-form By reporting side effects, you can help provide more information on the safety of NIFEDALAT 20 SR.

## 5. How to store NIFEDALAT 20 SR

Store all medicines out of reach of children.

Store in a dry place at or below 25 °C.

Keep the blisters in the carton until required for use.

Protect from light.

Do not use after the expiry date stated on the label / carton / bottle

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 NIFEDALAT 20 SR contains**

- Each film-coated tablet contains 20 mg of the active substance nifedipine, in a slow-release formulation.
- The other ingredients are polysorbate 80; maize starch; lactose , microcrystalline cellulose and magnesium stearate.
- Other ingredients for film-coating are polyethylene glycol 4000; hypermellose (hydroxypropyl-methylcellulose); titanium dioxide (E 171) and ferric oxide, red (E 172).

**What NIFEDALAT 20 SR looks like and contents of the pack**

Uniform pink to light red, round biconvex film-coated tablets.

NIFEDALAT 20 SR is available in aluminium foil and red coloured polypropylene blisters strips packed in cardboard cartons containing 60 tablets.

**Holder of Certificate of Registration**

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