

What is in this leaflet

1. What **NICARDIA- XL- 30** is used for
2. How **NICARDIA- XL- 30** works
3. Before you use **NICARDIA- XL- 30**
4. How to use **NICARDIA- XL- 30**
5. While you are using it
6. Side effects
7. Storage and Disposal of **NICARDIA- XL- 30** Product Description
8. Manufacturer and Product Registration Holder
9. Date of revision

What **NICARDIA- XL- 30** is used for

NICARDIA-XL-30 is used for treatment of treatment of coronary heart disease; chronic stable angina pectoris (angina of effort). Treatment of hypertension.

How **NICARDIA- XL- 30** works

NICARDIA-XL-30 is a tablet contains nifedipine. **NICARDIA-XL-30** works by relaxing and expanding the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decrease the strain on it. **NICARDIA-XL-30** also works by relaxing and expanding the blood vessels. This makes the blood to flow more easily and lower blood pressure.

Before you use **NICARDIA- XL- 30**

- When you must not use it

- When you are in cardiovascular shock, with narrowing of the aorta, with known hypersensitivity to nifedipine, with unstable angina and acute myocardial infarction (within the first 4 weeks).
- If you are allergic to nifedipine or to any other ingredient in **NICARDIA-XL-30**.
- If you are patients with extremely low blood pressure and existing heart muscle weakness

Pregnancy and lactation

Do not take **NICARDIA-XL-30** if you are pregnant, trying to get pregnant or think you may be pregnant.

Careful monitoring of blood pressure must be exercise when taking **NICARDIA-XL-30** with I.V. magnesium sulphate because an excessive falling of blood pressure may occur which would harm both mother and foetus.

Do not take **NICARDIA-XL-30** if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Please tell your doctor

- If you are a diabetic. The treatment for your diabetes may need to adjusted.
- If you are a kidney dialysis. If you have a very high blood pressure and low blood pressure, you might experience a sudden drop in blood pressure when you take **NICARDIA-XL-30**.

Please tell your doctor if you are taking any other medicines, including herbal products or any that you but without a prescription from a pharmacy, supermarket or health food shop.

- Taking other medicines

Check with your doctor before using the **NICARDIA-XL-30** if you are taking or using any other medicines. In particular:

- Other medicines to treat high blood pressure
- Rifampicin (an antibiotic)
- Ketoconazole (anti-fungal medicine)
- Ritonavir (to treat HIV)
- Fluoxetine or nefazodone (to treat depression)
- Cisapride (to treat reduced movements of the gullet and stomach)
- Valproic acid (to treat epilepsy)
- Cimetidine (to treat stomach ulcers)
- Diltiazem (to treat heart condition)

How to use **NICARDIA- XL- 30**

- How much to use

Always use **NICARDIA-XL-30** exactly as your doctor has told you. They may differ from the information contained in

this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help

- When to use it

Take this medication by mouth once daily on an empty stomach. The medication may be taken with or without food. This medication should swallowed whole with a little liquid, irrespective of meal times. should be swallowed whole, not bitten or divided. **NICARDIA-XL-30** tablet shall take once daily (1 x 30 mg/day). In general therapy should be initiated with 30 mg once daily. Depending on the severity of the disease and the patient's response the dose can be increased in stages up to 120 mg once daily.

- How long to use it

Continue taking **NICARDIA-XL-30** as long as your doctor recommended. Ask your doctor or pharmacist if you have any questions.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Over-dosage with **NICARDIA-XL-30** may produce severe blood pressure fall, loss of consciousness, heart rhythm disturbances and breathlessness.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking NICARDIA-XL-30. Tell your doctor immediately if you become pregnant while taking this medication.

- **Things you must not do**

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give NICARDIA-XL-30 to anyone else, even if they have the same symptoms or condition as you.

- **Things to be careful of**

Pregnancy and breast-Feeding

This medication should not be used during pregnancy. If you become pregnant or think you may be pregnant, inform your doctor immediately. Ask your doctor or pharmacist for advice before taking any medicines.

This medication passes into breast milk. It is proposed to delay breastfeeding for 3 to 4 hours after taking the medication. Consult your doctor before breast-feeding.

Driving and using machines

This medicine may cause dizziness, it may affect your ability to drive or use machines. Do not drive, use machines, or do any activity that required alertness until you are sure you can perform the activities safely.

Side effects

The most common side effects are headache, reddening of the face (flushing) and sensation of heat. Other side effects reported include:

Common side effects:

- Headache
- Flushing
- general feeling of being unwell
- constipation
- swelling, particularly of the ankles and legs

Uncommon side effects

- stomach pain (abdominal pain)
- unspecific pain
- chills
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- fainting
- irregular heartbeat (palpitations)
- dry mouth
- indigestion or upset stomach
- feeling sick (nausea)
- muscle cramps
- joint swelling
- sleep disorders
- anxiety or nervousness
- reddening of the skin
- nose bleeds
- nasal congestion
- sensation of spinning or whirling motion (vertigo)
- migraine
- dizziness
- trembling
- increase in the need to pass water (urinate)
- painful or difficult urination
- inability to achieve or maintain an erection (impotence)
- blurred vision
- temporary increase in certain liver enzymes

Rare Side effect:

- pins and needles
- inflammation of the gums, tender or swollen gums, bleeding gum

Other side effects

- 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
- a reduction in the number of white blood cells (leucopenia)
- a more severe decrease in a specific class of white blood cell (agranulocytosis)
- increased blood sugar (hyperglycaemia)

- decreased skin sensitivity (hypoesthesia)
- drowsiness (somnolence)
- eye pain
- chest pain (angina pectoris)
- 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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Food and Drink with NICARDIA-XL-30

Do not start taking NICARDIA-XL-30 within 3 days of taking grape fruits or grape juice. Grape fruit is known to increase the blood levels of NICARDIA-XL-30. The effect will last for 3 days.

Storage and Disposal of NICARDIA-XL-30

Storage

Keep out of the reach and sight of children.

Store below 30 °C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- **What it looks like**

It is Brown colored, round biconvex tablet, plain on one side & laser drilled hole on other side.

- **Ingredients**

- Active ingredient(s)
Nifedipine USP

- Inactive ingredients
Polyethylene Oxide NF (Polyox WSR N 80FP), Hypromellose USP 5 CPS Type 2910 (Methocel Premium E5LV), Potassium Chloride USP, Methyl Alcohol NF, Isopropyl Alcohol USP, Magnesium Stearate NF, Colloidal Silicon Dioxide NF, Polyethylene Oxide NF (Polyox WSR Coagulant), Sodium Chloride USP, Ferric Oxide Red NF, Magnesium Stearate NF, Colloidal Silicon Dioxide NF, Cellulose Acetate NF 398/10 Polyethylene Glycol 4000 NF, Acetone NF, Methyl Alcohol NF, Opadry Brown 03B86636 IH

- MAL number(s):

MAL19041004AZ

Manufacturer

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SDN BHD

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Date of revision

19.12.2019

Serial Number

NPRA(R2)19/135