

NIFELAT F.C TABLET

Nifedipine (10mg)

What is in this leaflet

1. What Nifelat is used for
2. How Nifelat works
3. Before you use Nifelat
4. How to use Nifelat
5. While you are using it
6. Side Effects
7. Storage and Disposal of Nifelat
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Nifelat is used for

Nifelat is indicated in the prevention and treatment of angina pectoris and in all types of arterial hypertension (high blood pressure).

How Nifelat works

Nifedipine, the active ingredient of Nifelat, belongs to the group of drugs named calcium channels blockers.

Calcium channels blockers impede the movement of calcium in the cells of the heart and the blood vessels. As a result, there is a relaxation of the blood vessels and an increase in the supply of blood and oxygen to the heart whilst the heart load is decreased.

Before you use Nifelat

- When you must not use it

Nifelat is contra-indicated in patients with hypersensitivity to Nifedipine or other dihydropyridines, in patients with cardiogenic shock, aortic constriction and unstable angina. Nifelat is also contra-indicated in pregnant women and in nursing mothers. The safety of the drug in malignant hypertension has not been established.

- Pregnancy

If you are pregnant, prepare for pregnant or suspect yourself are pregnant, please do not take Nifelat. Please consult your doctor or pharmacist before taking any medicine.

- Lactation

Nifedipine is excreted into maternal milk. Therefore, its administration is not recommended during nursing.

Consult your doctor or pharmacist before taking any medicine.

- Before you start to use it

You must tell your doctor if you are:

- if you are allergic to Nifedipine
- if you are pregnant or if you intend to get pregnant or if you are nursing
- if you are diabetic
- if you suffer from a serious form of hypotension
- if you have a poor cardiac reserve.

- Taking other medicines

A number of medicines interact with Nifelat and should not be used concomitantly. However, a few of them can be used concomitantly under special precautions. In this case, your doctor can change the dose or take other precautions, if needed. If you are about to take Nifelat, it is important to inform your doctor or pharmacist if you are taking any other medications and particularly any of the following: Cimetidine, quinidine

- Special precautions:

Nifelat can be taken with beta-blockers or other antihypertensive agents but the possibility of postural hypotension should be borne in mind. Nifelat cannot prevent possible rebound effects after cessation of other antihypertensive therapy. In case of ischaemic pain occurs after taking Nifedipine, the drug should be discontinued immediately. Caution should be exercised when administering the drug to patients with severe hypotension and to diabetics.

Nifelat contains lactose, therefore if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

How to use Nifelat

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. 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.

Adults: The tablets should be taken with

a little water. The recommended dose of Nifelat is 1-2 tablets two to three times daily, which can be titrated according to the patient's response. Maximum dose 20mg every 8 hours.

Elderly: They need lower maintenance doses.

Children:

Nifelat is not indicated for children.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Nifelat for as long as your doctor recommends.

- If you forget to use it

If you must take the drug continuously and you miss taking a dose, you should take the missed dose as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take double doses. If you miss taking a number of doses consult your doctor.

- If you use too much (overdose)

In case of taking a dose larger than normal stop taking the drug and contact your doctor immediately. Symptoms that may appear after an overdosage of Nifelat are severe hypotension because of vasodilation (widening of blood vessel), tachycardia (resting heart rate more than 100 beats per minutes) or bradycardia (resting heart rate less than 60 beats per minutes), cardiac block (heart block), cardiogenic shock with pulmonary oedema (inadequate circulation of blood with accumulation of fluids in lung), nausea, vomiting, dizziness, lethargy, flushing. In case of overdosage gastric lavage and administration of activated charcoal is recommended.

Contact your doctor even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Your doctor will decide the most suitable treatment for you.

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Consumer Medication Information Leaflet (RiMUP)

Nifedipine (10mg)

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 Nifelat.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Consult your doctor or pharmacist first before taking any other medication.
- In case of overdose contact your doctor immediately.
- Keep this leaflet in a safe place. You may need to read it again.

- 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.
- This medicine was prescribed for you personally and you should not pass it on to others. It can be harmful, even if they have the same symptoms or condition as you.

- Things to be careful of

Nifedipine may rarely cause headaches, dizziness, nausea, and fatigue to such a degree that it may affect the patient's reaction time.

Side Effects

As with all medicines Nifelat may cause undesirable effects.

Inform your doctor if you experience any of the following side effects:

The most common side-effects of Nifelat are dizziness, headache, flushing, hypotension and peripheral oedema. Ischaemic chest pain may occur at the start of treatment. There have been reports of abnormalities in liver function due to hypersensitivity reactions, and gingival hyperplasia (increase in size of gum) has been reported.

Other less commonly reported side-effects include, rash, nausea, lethargy and increased frequency of urination

If you experience undesirable effects that are not mentioned above, please inform your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Nifelat

- Storage

Keep below 25°C, protected from light and moisture and in safe place away from the reach and sight of children.

Product expiry date is shown on the inner and outer packaging. In case the expiry date has lapse, do not use.

- 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

Yellow, round, scored, film-coated tablets with remedica's logo in one side.

- Ingredients

Active ingredient: Nifedipine

Inactive ingredients: Microcrystalline Cellulose, Lactose, Colloidal Silicon Dioxide, Magnesium Stearate, Pregelatinized Starch, Hypromellose, Macrogol 400, Titanium Dioxide, Talc, Quinoline Yellow E104.

- MAL number:

MAL19913451A

Manufacturer

Remedica Ltd., Limassol Industrial Estate, Limassol, Cyprus, EU.

Product Registration Holder

LF Asia (Malaysia) Sdn Bhd (719-V)
Lot 6, Persiaran Perusahaan, Seksyen 23,
40300 Shah Alam,
Selangor Darul Malaysia

Date of Revision

22/01/2014