

NYEFAX RETARD™

nifedipine

20 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking NYEFAX RETARD

This leaflet answers some common questions about NYEFAX RETARD. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NYEFAX RETARD against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What NYEFAX RETARD™ is used for

NYEFAX RETARD is used for the treatment of coronary heart disease, angina pectoris - exercise induced chest pain, hypertension - high blood pressure.

NYEFAX RETARD contains nifedipine, which belongs to a group of medicines called calcium antagonist. For angina, NYEFAX RETARD works by relaxing and expanding the arteries supplying the heart which allows more blood and oxygen to reach the heart and this decreasing the strain on it. For high blood pressure, NYEFAX RETARD works by relaxing and expanding the blood vessels which makes the blood flow more easily and lowers blood pressure.

NYEFAX RETARD does not change the amount of calcium in your blood or bones.

Your doctor may have prescribed NYEFAX RETARD for another reason.

Ask your doctor if you have any questions about why NYEFAX RETARD has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take NYEFAX RETARD™

When you must not take it

Do not take NYEFAX RETARD if you have an allergy to:

- nifedipine
- other calcium channel blockers
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching

Do not take NYEFAX RETARD:

- If you have ever had a cardiovascular shock- a collapse caused by heart problem during which you become breathless, pale, have a dry mouth and cold sweat due to a very low blood pressure due to a failing heart.
- if you are taking the medicine rifampicin (antibacterial).

Do not take this medicine if you are pregnant.

if you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not breastfeed if you are taking this medicine.

The active ingredient in NYEFAX RETARD passes into breast milk and there is a limited information on the possible effects of nifedipine on infants.

Do not give this medicine to children and adolescents under the age of 18 years.

Safety and effectiveness in children and adolescents younger than 18 years have not been established.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tempering.

If you are not sure whether you should start using NYEFAX RETARD, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 1. you have allergies to:**
 - Any other medicines
 - Any other substances, such as foods, preservatives or dyes.
- 2. you have, or have had, the following medical conditions:**
 - hypotension – low blood pressure
 - heart failure
 - severe narrowing of the aorta
 - impaired liver function
- 3. you are pregnant or intend to become pregnant.**

Ask your doctor for advice before taking this medicine.
- 4. you are breastfeeding planning to breastfeed.**

Ask your doctor for advice before

taking this medicine.

5. you are planning to father a child by *in vitro* fertilisation.

Tell your doctor that you are taking NYEFAX RETARD. NYEFAX RETARD may affect sperm function.

If you have not told your doctor about any of the above, tell them before you start taking NYEFAX RETARD.

NYEFAX RETARD contains lactose.

If you have intolerance to some sugars, tell your doctor before taking it.

Tell your doctor if you eat or drink grapefruit juice regularly, including in the last 3 days before starting NYEFAX RETARD.

Do not have grapefruit while you are taking NYEFAX RETARD because this can cause unwanted changes in the blood pressure reducing the effect of this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking NYEFAX RETARD.

Some medicines may interfere with NYEFAX RETARD. These include:

- other hypertensive medications
- rifampicin- medicine used to treat tuberculosis and other serious infections
- beta-blockers, e.g. metoprolol
- digoxin, quinidine- medicines used to treat arrhythmias (fast or irregular heartbeats)
- diltiazem - a medicine used to enlarge blood vessels
- phenytoin - a medicine used to treat epilepsy

- cisapride or cimetidine - medicines used to treat stomach ulcers and heartburn
- erythromycin, quinupristin, dalbapristin - medicines used to treat bacterial infections
- anti-depressants e.g., fluoxetine and nefazodone
- medicines used to treat HIV e.g., ritonavir
- medicines used to treat fungal infections e.g., ketoconazole
- tacrolimus - an immunosuppressant
- carbamazepine, phenobarbitone, valproic acid - medicines used to treat epilepsy

These medicines may be affected by NYEFAX RETARD or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NYEFAX RETARD.

How to take NYEFAX RETARD™

How much to take

Carefully follow all directions given to you by your doctor. Their directions 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.

Your doctor will decide the dose depending on your medical condition and response to treatment. If you have impaired liver function, it is important you undergo monitoring.

How to take it

NYEFAX RETARD tablets should be taken whole with some water, independently of meals or as instructed by your doctor or pharmacist. The tablets must not be chewed, halved or broken up.

Do not take them with grapefruit juice.

When to take it

Take your prescribed dose at the usual time of day, waiting at least 12 hours before taking the next dose.

How long to take it

Your doctor will determine the duration of treatment with NYEFAX RETARD.

If you forget to take it

Take your normal dose immediately and continue taking your tablets as prescribed, waiting 12 hours before taking your next dose.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking NYEFAX RETARD™

Things you must do

Be sure to keep all of your doctor's appointments so that your progress can be checked.

If you become pregnant while you are taking NYEFAX RETARD tablets, tell your doctor immediately.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking NYEFAX RETARD tablets.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking NYEFAX RETARD.

Things you must not do

Do not give NYEFAX RETARD tablets to anyone else, even if they have the same condition as you.

Do not eat grapefruit or drink grapefruit juice while you are taking this medicine.

Grapefruit can cause unwanted changes in the blood pressure reducing the effect of NYEFAX RETARD.

Do not stop taking NYEFAX RETARD tablets, or lower the dosage, without checking with your doctor. Your doctor may want you to gradually reduce the amount you are using before stopping completely.

Do not let yourself run out of tablets over the weekend or holidays.

Things to be careful of

Be careful driving or operating machinery until you know how NYEFAX RETARD affects you. It may cause dizziness or fainting in some people, especially after the first start taking medicine, change dose or drink alcohol.

If you have angina, be careful not to overdo physical activities when you first start taking NYEFAX RETARD.

You may feel better when you start taking it, but you will still need time to improve your physical fitness.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much NYEFAX RETARD.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs of an overdose include feeling dizzy and fainting due to drop in blood pressure, irregular or rapid heartbeats, shortness of breath, shock and loss of consciousness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NYEFAX RETARD.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

The list below includes the more common side effects of your

- medicine. headache
- constipation
- feeling dizzy
- generally feeling unwell
- general swelling and/or swelling of the arms, ankles or legs

Your doctor may need to monitor your liver function, as NYEFAX RETARD can increase your liver enzymes. You may not experience any specific symptoms.

If any of the following happen, stop taking NYEFAX RETARD and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- chest pain
- severe, sudden generalised allergic reaction (e.g. difficulty in breathing, drop of blood pressure, fast pulse),
- swelling of the face, lips, tongue,
- or other parts of the body

- fast heartbeat (tachycardia)
- shortness of breath or difficulty breathing
- rash, itching or hives on the skin
- signs of liver problems such as yellowing of the skin and/or eyes (jaundice)
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers

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

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some people.

After taking NYEFAX RETARD™

Storage

Keep your tablets in the pack and protect from light and moisture until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store NYEFAX RETARD in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

NYEFAX 20 mg Film-Coated Tablet: Pale pink, biconvex, film-coated tablet of 7 mm diameter and comes in bottles of 100 tablets or blister packs of 30 tablets. Not all pack sizes may be marketed.

Ingredients

Active ingredient(s):

- nifedipine 20 mg

Inactive ingredients:

- iron oxide black
- iron oxide red
- lactose monohydrate
- macrogol 4000
- magnesium stearate
- methylcellulose
- microcrystalline cellulose
- polysorbate 80
- pregelatinised maize starch
- purified water
- titanium dioxide

Sponsor details

NYEFAX RETARD is supplied in New Zealand by:
Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

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