160 mm

500 mm

AXP055FMJ

Package leaflet: Information for the patient

NEOFEL XL 2.5, 5 & 10 MG PROLONGED RELEASE TABLETS (felodipine)

The name of this medicine is Neofel XL Prolonged Release Tablets (felodipine), which will be referred to as Neofel XL throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others; it may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT NEOFEL XL ARE AND WHAT THEY ARE USED FOR

The active ingredient in Neofel XL is felodipine which is one of a group of medicines called dihydropyridine calcium antagonists. These work by blocking the entry of calcium into muscle cells. Neofel XL (felodipine) affects the muscle in blood vessels more than other muscles. It causes a relaxation of the muscle and a widening of the blood vessels. As the blood vessels get wider, blood pressure falls and the heart does not need to work so hard to pump blood around the body, reducing the risk of angina.

Neofel XL is used to treat high blood pressure (hypertension) and prevent attacks of angina (a painful condition where there is a lack of blood and oxygen to the heart).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEOFEL XL

Do not take Neofel XL:

- If you are **pregnant**, planning to become pregnant or you suspect you are pregnant
- If you are **allergic** to **felodipine** or any of the **other ingredients** of this medicine (listed in Section 6)
- If you suffer from **uncompensated heart failure**
- If you have had a **heart attack** (myocardial infarction) within the last 4 weeks
- If you **suffer from severe chest pain due to a lack of blood and oxygen to the heart (unstable angina pectoris)**
- If you have **narrowing of one of the valves** in the heart (aortic stenosis)
- If you have or develop **cardiogenic shock** (where the heart is unable to supply sufficient blood to the body)

Warnings and precautions

Talk to your doctor or pharmacist before taking Neofel XL if you:

- have a **rapid heartbeat (tachycardia)**
- have a **liver disorder**
- are **breast-feeding**
- **suffer from a condition which affects the chambers of your heart and may prevent them from working properly (left ventricular dysfunction)**

Neofel XL like other blood-pressure lowering medicinal products may in rare cases lead to pronounced low blood pressure which in some patients may result in an inadequate supply of blood to the heart. Symptoms of excessive low blood pressure and inadequate blood supply to the heart itself, frequently include dizziness and chest pain. If you experience these symptoms, seek emergency care immediately.

Taking Neofel XL may cause your gums to become swollen. Practice good oral hygiene to help avoid your gums from swelling (see section 4).

Children

The use of **Neofel XL** is not recommended in children

Other medicines and Neofel XL

Tell your doctor if you are taking, have recently taken or might take any other medicines. Medicines containing St. John's wort (*Hypericum perforatum*) (herbal product used to treat depression) may reduce the effect of Neofel XL and should therefore be avoided.

Below are examples of some medicines/herbal remedies which may decrease or increase the effect of Neofel XL:

- other medicines for treating high blood pressure including diuretics (water tablets)
- cimetidine for the treatment of stomach ulcers
- erythromycin, clarithromycin and rifampicin used to treat bacterial infections
- nelfinavir, ritonavir, indinavir, efavirenz and nevirapine for the treatment of HIV
- ketoconazole and itraconazole used to treat fungal infections
- medicines for the treatment of convulsions or epilepsy (e.g. phenytoin, carbamazepine or phenobarbital).
- tacrolimus an immunosuppressive drug used to prevent organ transplant rejection

It may still be all right for you to take Neofel XL and your doctor will be able to decide what is suitable for you. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Neofel XL with food and drink

It is recommended that Neofel XL should be taken without food or after a light meal not rich in fat or carbohydrate.
Grapefruit juice can affect the amount of Neofel XL (felodipine) in the blood; therefore patients should not consume grapefruit juice during treatment with this medicine.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, likely to become pregnant or suspect you are pregnant. Tell your doctor or pharmacist if you are breast-feeding and they will decide if this medicine is right for you. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Neofel XL can have minor or moderate influence on your ability to drive and use machines. If you experience headache, nausea, dizziness or fatigue your ability to react may be impaired. Caution is recommended especially at the start of treatment.

Important information about some of the ingredients of Neofel XL

Neofel XL contains lactose. If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicine.

3. HOW TO TAKE NEOFEL XL

Dosage

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The label on the carton will tell you how many tablets you should take and when. Your doctor will decide on the right starting dose for you and on any increase in the dose depending on your condition and whether you are taking any other medicines. Do not change your dose unless your doctor tells you to do so.

The recommended doses for Neofel XL are as follows:

Hypertension (High Blood Pressure)

The recommended starting dose is 5 mg once a day. If necessary, the dose may be increased by your doctor to give you the best response. The recommended maintenance dose is 5 mg a day.
If you are elderly, your doctor may start you on a lower dose of 2.5 mg once a day.

Pharmacode

Pharmacode

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Cipla Inventory Code

Back

160 mm

500 mm

Angina
The recommended starting dose is 5 mg once a day. This may be increased by your doctor to 10 mg once a day if necessary.

Neofel XL are for use in Adults only.

Method of Administration
Neofel XL should be swallowed whole with half a glass of water. The tablets should be taken in the morning without food or after a light meal not rich in fat or carbohydrate. Patients should not consume grapefruit juice during treatment with this medicine. The tablets should **not be divided, chewed** or **crushed**.

If you take more Neofel XL than you should
If you have accidentally taken more than your prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you. The most common signs and symptoms of overdose are a fall in blood pressure (causing dizziness and light-headedness) accompanied by a drop in heart rate.

If you forget to take Neofel XL
It is important that you take your medicine every day. However, if you forget to take one or more doses, take your next dose when it is due and then go on as prescribed. Do not take a double dose to make up for a forgotten dose.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any of the following symptoms after taking these tablets, **you should stop taking Neofel XL and contact your doctor immediately:**
- **hypersensitivity or allergic reactions including symptoms such as fever, sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.**
- **other allergic reactions, urticaria (hives)**

The following effects have been reported:
Very common: (may affect more than 1 in 10 people)
- headache
- flushing
- swollen ankles (peripheral oedema)

Uncommon: (may affect up to 1 in 100 people)
- tingling or numbness of the skin (paraesthesia) e.g. pins and needles, skin rash, itching (pruritus)
- fast heart beat (tachycardia), palpitations
- feeling sick (nausea), abdominal (stomach) pain
- tiredness (fatigue)
- low blood pressure (hypotension)

Rare: (may affect up to 1 in 1,000 people)
- fainting (syncope), reduced blood supply to the heart muscle (myocardial ischaemia)
- impotence, sexual dysfunction
- being sick (vomiting)
- joint or muscle pain (arthralgia, myalgia)

Very rare: (may affect up to 1 in 10,000 people)
- sensitivity of skin to sunlight (exposure to sunlight may occasionally aggravate skin rash)
- gum swelling (gum hyperplasia, gingivitis). Patients with gingivitis/periodontitis an inflammation of the mouth and gums have reported mild gum swelling.
- increased liver enzymes (symptoms may include feeling sick or more tired than usual, stomach pain or a yellowing of the skin or whites of the eyes)
- small vessel inflammatory disease (leukocytoclastic vasculitis)
- pollakisuria (abnormal frequent passage of urine)

Aggravation of angina has been reported in a small number of patients when first starting treatment.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine

5. HOW TO STORE NEOFEL XL

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Do not store your tablets above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Neofel XL contain:
The active substance is felodipine. Each tablet contains 2.5, 5 or 10 mg of felodipine.
The other ingredients are lactose monohydrate, microcrystalline cellulose, hypromellose, povidone, propyl gallate, colloidal anhydrous silica, magnesium stearate, ferric oxide (E172), titanium dioxide (E171), talc and propylene glycol. (See section 2 **Important information about some of the ingredients of Neofel XL**).

What Neofel XL look like and the contents of the pack:
Neofel 2.5 mg XL Prolonged Release Tablets are yellow, round, biconvex film coated prolonged-release tablets with imprint '2.5'.
Neofel 5 mg XL Prolonged Release Tablets are light pink, round, biconvex film coated prolonged-release tablets with imprint '5'.
Neofel 10 mg XL Prolonged Release Tablets are reddish brown, round, biconvex film coated prolonged-release tablets with imprint '10'.
Your medicine is available in blister packs of 10, 20, 28, 30, 50, 56 or 100 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder:
Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place,
Ashford, Kent, England, TN23 1FB.

Manufacturer responsible for batch release:
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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Pharmacode

Pharmacode

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Cipla Inventory Code

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