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Pharmacode

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AXP055FMK 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
2. What you need to know before you take Neofel XL
3. How to take Neofel XL
4. Possible side effects
5. How to store Neofel XL
6. Contents of the pack and other information

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)
- If you have chest pain of recent onset, or angina pectoris that is lasting for more than 15 minutes or longer or is more severe than usual.
- If you have disease of a heart valve or heart muscle, until you have talked to your doctor.

Warnings and precautions

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.

Talk to your doctor before taking Neofel XL, especially if you have problems with your liver. 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
- neftinavir, ritonavir, indinavir, efavirenz and nevirapine for the treatment of HIV
- ketoconazole and itraconazole used to treat fungal infections
- medicines for the treatment of convulsions, anxiety, sleeping problems 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.

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.

Neofel XL with food and drink

Do not drink grapefruit juice if you are treated with Neofel XL, as this may increase the effect of Neofel XL and the risk of side effects.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, likely to become pregnant or suspect you are pregnant. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Neofel XL is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

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.

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.

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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 take more than the recommended number of doses of Neofel XL, you may suffer from very low blood pressure and sometimes palpitations, high or, rarely, slow heart rate. Therefore, it is very important that you take the number of doses prescribed by your doctor. If you experience symptoms such as feeling faint, light-headedness or dizziness, contact your doctor immediately.

If you forget to take Neofel XL
If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Neofel XL
If you stop taking this medicine your condition may return. Please consult your doctor and seek advice before you stop taking Neofel XL. Your doctor will advise you how long to take your medicine. If you have any further questions on the use of this medicine, ask your doctor.

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 raised lumps on your skin (weals), fever, swelling of the eyelids, face, lips or throat.

The following undesirable effects have been identified. Most of these reactions appear at start of treatment or after a dose increase. Should such reactions occur, they are usually brief and diminish in intensity with time. If you experience any of the following symptoms and they persist, please tell your doctor. Mild enlargement of the gums has been reported in patients with an inflammation in the mouth (gingivitis/periodontitis). The enlargement can be avoided or reversed by careful oral hygiene.

Very common: (may affect more than 1 in 10 people)

- swollen ankles (peripheral oedema)

Common: (may affect up to 1 in 10 people)

- Headache
- Flushing

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), burning, pricking
- fast heart beat (tachycardia), palpitations
- feeling sick (nausea), abdominal (stomach) pain
- tiredness (fatigue), dizziness
- 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)
- nettle rash

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)
- Hypersensitivity reactions such as fever or swelling of the lips and tongue

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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