PACKAGE LEAFLET: INFORMATION FOR THE USER

Felotens XL 2.5mg, 5mg and 10mg Prolonged-release Tablets

Active ingredient: Felodipine

xxxxx.xxxxx

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Felotens XL Tablets are and what they are used for

Felotens XL Tablets belong to a group of medicines called dihydropyridine-type calcium channel blockers. These work by relaxing the smooth muscle in the blood vessel walls and opening the blood vessels. This then lowers the blood pressure.

Felotens XL Tablets are used to:
- treat patients with high blood pressure (essential hypertension).

2. Before you take Felotens XL Tablets

DO NOT take Felotens XL Tablets if you:
- are allergic (hypersensitive) to felodipine, other similar compounds (dihydropyridine-type calcium channel blockers) or any of the other ingredients in the tablets (see section 6. "Further information" at the end of this leaflet)
- have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
- have a very low pulse and blood pressure (cardiogenic shock)
- have severe narrowing (stenosis) of the heart valves (mitral or aortic valve)
- suffer from an enlarged heart muscle (obstructive hypertrophic cardiomyopathy)
- get chest pain (unstable angina pectoris)
- have suffered a heart attack within the last two months
- have untreated and/or decompensated heart failure, causing swelling of the extremities, weakness, and shortness of breath
- have severely reduced liver function
- are or may be pregnant
- suffer from acute porphyria (a disease that causes stomach problems and discolouration of the urine).

Take special care with Felotens XL Tablets if you:
- have severely reduced kidney function
- have mild to moderate reduced liver function
- suffer with stable heart failure
- suffer with fast heartbeat (tachycardia)
- suffer with narrowing (stenosis) of the heart valves (mitral or aortic valve)
- have conduction disturbances in the heart (e.g. 2nd or 3rd degree atrioventricular block).

Felodipine could cause an extensive fall in blood pressure resulting in fast heartbeat (tachycardia). This may lead to a restriction in blood supply (myocardial ischaemia) and stroke in sensitive patients.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, herbal medicines, or natural products.

Especially:
- other medicines that lower blood pressure such as hydrochlorothiazide, beta blockers (to treat high blood pressure), nitrates (to control coronary heart disease and chest pain) or tricyclic antidepressants (to treat depression)
- amiodarone, diltiazem or verapamil (to treat heart problems)
- digoxin (to treat heart failure)
- fluconazole, itraconazole, ketoconazole, miconazole, or voriconazole (to treat fungal or yeast infections)
- erythromycin, clarithromycin, or telithromycin (macrolide antibiotics)
- rifampicin (to treat tuberculosis)
- ciclosporin, tacrolimus (to suppress immune system e.g. after organ transplantation)
- phenobarbital, phenytoin, or carbamazepine (to treat epilepsy)
- cimetidine (to treat heartburn and stomach ulcers)
- nevirapine, ritonavir, sakinavir (to treat HIV infection)
- herbal medicines containing St. John's wort (Hypericum perforatum).

Taking Felotens XL Tablets with food and drink
Take Felotens XL Tablets on an empty stomach or with a light meal. The tablets should not be taken with a high fat meal.

Do not drink grapefruit juice during treatment with Felotens XL Tablets as this may make the tablets work too strongly. If you have any questions, please ask your doctor.

Pregnancy and breast-feeding
Felodipine must not be taken during the whole pregnancy. If you think you are pregnant, plan to get pregnant or become pregnant while using Felotens XL Tablets stop using the medicine immediately and consult your doctor as soon as possible.

Felodipine is excreted in breast milk, therefore the use of Felotens XL Tablets is not recommended whilst breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Felotens XL Tablets can cause dizziness or tiredness. These effects are more likely to occur at the start of treatment, after dose increases, or after taking alcohol at the same time. If you are affected, do not drive or operate machinery.

Important information about some of the ingredients of Felotens XL Tablets
This medicine contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Felotens XL Tablets

Always take Felotens XL Tablets exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

The usual doses are described below.

Adults Initially, 5mg once daily. If needed, the doctor may increase the dose to 10mg daily or may prescribe an additional medicine to lower blood pressure. The maximum daily dose is 10mg felodipine.

Elderly The doctor will decide your starting dose.

Children Not recommended.

Taking the tablets
- Swallow these tablets whole at the same time of the day (e.g. in the morning) with a glass of water. Do not crush or chew them.
- Do NOT take the tablets with grapefruit juice, as this may make Felotens XL Tablets work too strongly.
- Take the tablets on an empty stomach or with a light meal. The tablets should not be taken with a high fat meal.
- Take this medicine for as long as your doctor tells you to. It may be dangerous to stop without your doctor's advice.

If you take more Felotens XL Tablets than you should
Do not take more tablets than your doctor tells you to. If you ever take too many, go to the nearest hospital casualty department or tell your doctor immediately. Take the container and any remaining tablets with you to show to the doctor. An overdose may lead to light-headedness, fainting and dizziness caused by very low blood pressure and in rare cases slowed heartbeat (bradycardia).

If you forget to take Felotens XL Tablets
If you forget to take a dose, take one as soon as you remember. Then go on as before. Do not take two doses at the same time to make up for a forgotten dose. If you are worried, ask your pharmacist or doctor for advice.

If you stop taking Felotens XL Tablets
Do not stop treatment early because felodipine can be associated with withdrawal symptoms.

Please read the back of this leaflet.

If you stop taking the tablets too quickly you may develop high blood pressure again. Talk to your doctor before you stop taking the tablets and follow the advice.

4. Possible side-effects

Like all medicines, Felotens XL Tablets may cause side-effects, although not everyone gets them. Evaluation of the side-effects is based on the following frequencies:

Very common:	In more than 1 in 10 patients treated
Common:	In less than 1 in 10, but more than 1 in 100 patients treated
Uncommon:	In less than 1 in 100, but more than 1 in 1,000 patients treated
Rare:	In less than 1 in 1,000, but more than 1 in 10,000 patients treated
Very rare:	In less than 1 in 10,000 patients treated, including single reports
Not known:	frequency cannot be estimated from the available data

Stop taking Felotens XL Tablets and contact your doctor if you have an allergic reaction such as swelling of the face, lips, tongue, mouth and throat, which may cause shortness of breath or difficulty swallowing.

Tell your doctor if you notice any of the following side-effects.

Very common:
- headache
- tinnitus (ringing or buzzing in the ears)
- flushing.

These effects are more likely to occur at the start of treatment or after dose increases and may settle with continued use.

Common:
- chest pain (angina pectoris) or worsening (increase in frequency, duration and severity) of chest pain in patients with pre-existing angina pectoris. This is more likely at the beginning of treatment
- swelling of extremities (in particular the ankles, the degree of ankle swelling is dose related).

Uncommon:
- pins and needles (paraesthesia)
- dizziness
- fatigue
- restlessness
- palpitations
- fast heartbeat (tachycardia)
- very low blood pressure (hypotension)
- fainting (syncope)
- shortness of breath (dyspnoea)
- gastrointestinal complaints (e.g. feeling sick (nausea) or being sick (vomiting), diarrhoea, constipation, stomach pain)
- skin and hypersensitivity reactions such as itching skin (pruritus), hives (urticaria), rash (exanthema)
- sensitivity to light (photosensitization)
- increased sweating
- joint or muscle pain (myalgia and arthralgia)
- tremors
- weight gain.

Rare:
- palpable, normally painful purple colouration of the skin (cutaneous vasculitis, very rarely leucocytoclastic vasculitis).
- rash and/or itching skin
- erection disorders or impotence
- inflammation or swelling of the gums (gum hyperplasia and gingivitis)
- increased need to pass urine (pollakiuria)
- fever.

Very rare:
- heart attack (myocardial infarction)
- liver function problems seen as raised transaminase levels in blood tests
- scaling skin reactions (exfoliative dermatitis)
- erection disorders
- enlargement of breast tissue in males (gynecomastia)
- heavy menstruation (menorrhagia)
- angio-oedema (serious allergic reaction which causes swelling of the face or throat).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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
By reporting side effects you can help provide more information on safety of this medicine.

5. How to store Felotens XL Tablets

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not take Felotens XL after the expiry ("use before") date, which is stated on the carton. The expiry date refers to the last day of that month.

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.

6. Further information

What Felotens XL contains
- The active substance is felodipine.
- Each 2.5mg prolonged-release tablet contains 2.5mg of felodipine.
- Each 5mg prolonged-release tablet contains 5mg of felodipine.
- Each 10mg prolonged-release tablet contains 10mg of felodipine.
- The other ingredients in the tablet core are:
  - lactose monohydrate (2.5mg tablet contains 25.2mg lactose; 5mg tablet contains 22.75mg lactose; 10mg tablet contains 20.38mg lactose)
  - microcrystalline cellulose
  - hypromellose
  - povidone
  - propyl gallate
  - colloidal anhydrous silica
  - magnesium stearate.
- The other ingredients in the film coating are:
  - hypromellose
  - titanium dioxide (E171)
  - red and yellow iron oxide (E172)
  - talc
  - propylene glycol

What Felotens XL 2.5mg, 5mg and 10mg Prolonged-release Tablets look like and the contents of the pack

Felotens XL 2.5mg: Yellow, round, biconvex, film-coated prolonged-release tablet with imprint 2.5.

Felotens XL 5mg: Light pink, round, biconvex, film-coated prolonged-release tablet with imprint 5.

Felotens XL 10mg: Reddish brown, round, biconvex, film-coated prolonged-release tablet with imprint 10.

Blister packs with pack sizes of: 10, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100, 250, 500 and 1000 prolonged-release tablets.

Not all pack sizes may be marketed.

POM

PL 06831/0225	**Felotens XL 2.5mg Prolonged-release Tablets**
PL 06831/0226	**Felotens XL 5mg Prolonged-release Tablets**
PL 06831/0227	**Felotens XL 10mg Prolonged-release Tablets**

Marketing Authorisation Holder and Manufacturer

MA holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield, HD7 5QH,
UK.

Manufacturer:
STADA Arzneimittel AG,
Stadastraße 2-18,
D-61118 Bad Vilbel,
Germany.

Centrafarm Services B.V.,
Nieuwe Donk 9,
4879 AC Etten-Leur,
Netherlands.

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