PHARMACODE

PACKAGE LEAFLET:
INFORMATION FOR THE USER

MORNINGSIDE HEALTHCARE

Delofine XL

2.5 mg, 5 mg and 10 mg Prolonged-Release Tablets

Felodipine

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 any further questions, ask your doctor or 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 Delofine XL Prolonged-Release Tablets are and what they are used for
2. What you need to know before you take Delofine XL Prolonged-Release Tablets
3. How to take Delofine XL Prolonged-Release Tablets
4. Possible side effects
5. How to store Delofine XL Prolonged-Release Tablets
6. Contents of the pack and other information

1. What Delofine XL Prolonged-Release Tablets are and what they are used for

Delofine XL Prolonged-Release Tablets contain the active substance felodipine. This belongs to a group of medicines called calcium antagonists. It lowers blood pressure by dilating small blood vessels. It does not negatively affect the heart function.

Delofine XL is used in the treatment of high blood pressure (hypertension) and heart and chest pain brought on by for example exercise or stress (angina pectoris).

2. What you need to know before you take Delofine XL Prolonged-Release Tablets

Do not take Delofine XL Prolonged-Release Tablets:

- if you are pregnant. You should tell your doctor as soon as possible if you become pregnant while using this medicine,
- 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 acute myocardial infarction (heart attack),
- 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

Delofine 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 Delofine XL, especially if you have problems with your liver.

Taking Delofine 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 Delofine XL is not recommended in children.

Other medicines and Delofine XL Prolonged-Release Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as some medicines may affect the way Delofine XL works.

Examples are:

- cimetidine (medicine to treat gastric ulcers),
- erythromycin (medicine to treat infections),
- itraconazole (medicine to treat fungi),
- ketoconazole (medicine to treat fungi),
- medicines to treat HIV protease inhibitors (such as ritonavir),
- medicines to treat HIV infection (such as efavirenz, nevirapine),
- phenytoin (medicine to treat epilepsy),
- carbamazepine (medicine to treat epilepsy),
- rifampicin (medicine to treat infections),
- barbiturates (medicine to treat anxiety, sleeping problems and epilepsy),
- tacrolimus (medicine used in organ transplantations).

Medicines containing St. John's wort (Hypericum perforatum) (herbal product used to treat depression) may reduce the effect of Delofine XL and should therefore be avoided.

Delofine XL Prolonged-Release Tablets with food and alcohol

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

Pregnancy and breast-feeding

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.

Pregnancy
Do not take Delofine XL if you are pregnant.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Delofine 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

Delofine 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.

Delofine XL Prolonged-Release Tablets contain lactose, castor oil and sodium

Delofine XL Prolonged-Release Tablets contain lactose that is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Delofine XL Prolonged-Release Tablets contain castor oil, which may cause stomach upset and diarrhoea.

Delofine XL Prolonged-Release Tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Delofine XL Prolonged-Release Tablets

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Delofine XL Prolonged-Release Tablets should be taken in the morning and be swallowed with water. The tablet must not be divided, crushed or chewed. This medicine can be taken without food or following a light meal not high in fat or carbohydrates.

Hypertension

Treatment should be started with 5 mg once a day. If necessary, your doctor may increase the dose or add another blood-pressure lowering medicine. The usual dose when treating this disease for a long time is 5-10 mg once a day. In elderly patients, a starting dose of 2.5 mg daily may be considered.

Stable angina pectoris

Treatment should be started with 5 mg once a day and if needed, your doctor may increase the dose to 10 mg once a day.

If you have liver problems
The level of felodipine in your blood may be increased. Your doctor may lower the dose.

Elderly people
Your doctor may initiate treatment with the lowest available dose.

If you take more Delofine XL Prolonged-Release Tablets than you should
If you take more than the recommended number of doses of Delofine 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 Delofine XL Prolonged-Release Tablets
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 Delofine XL Prolonged-Release Tablets
If you stop taking this medicine your condition may return. Please consult your doctor and seek advice before you stop taking Delofine 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 or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen to you, stop taking Delofine XL and tell a doctor straight away:
- Hypersensitivity and allergic reactions: The signs may include raised lumps on your skin (weals) or swelling of your face, lips, mouth, tongue 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
- Ankle swelling.

Common: may affect up to 1 in 10 people
- Headache.
- Flushing.

Uncommon: may affect up to 1 in 100 people
- Abnormally rapid heart rate.
- Palpitations.
- Too low blood pressure (hypotension).
- Nausea.
- Abdominal pain.
- Burning/prickling/numbness.
- Rash or itching.
- Fatigue.
- Dizziness.

Rare: may affect up to 1 in 1,000 people
- Fainting.
- Vomiting.
- Nettle rash.
- Pain in joints.
- Muscular pain.
- Impotence/sexual dysfunction.

Very rare: may affect up to 1 in 10,000 people
- Gingivitis (swollen gums).
- Increased liver enzymes.
- Skin reactions due to increased sensitivity to sunlight.
- Inflammation of small blood vessels of the skin.
- A need to pass water frequently.
- Hypersensitivity reactions such as fever or swelling of the lips and tongue.

Other undesirable effects may occur. If you have any bothersome or unusual reaction while taking Delofine XL, check with your doctor right away.

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 Delofine XL Prolonged-Release Tablets

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 and blister foil after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Delofine XL Prolonged-Release Tablets contain
Each prolonged-release tablet contains either 2.5 mg, 5 mg or 10 mg of felodipine as the active ingredient.

The other excipients are:
Tablet core: hydroxypropylcellulose (E463), hypromellose (E464), lactose monohydrate, macrogolglycerol hydroxystearate, aluminium magnesium silicate and sodium stearyl fumarate.

Tablet coating: Delofine XL 2.5 mg and 5 mg: hypromellose (E464), titanium dioxide (E171), macrogol and iron oxide yellow (E172).

Delofine XL 10 mg: hypromellose (E464), titanium dioxide (E171) and macrogol.

What Delofine XL Prolonged-Release Tablets look like and contents of the pack
Delofine XL 2.5 mg Prolonged-Release Tablets are yellow circular, biconvex film-coated tablets debossed with 'L26' on one side and plain on the other side.

Delofine XL 5 mg Prolonged-Release Tablets are light yellow circular, biconvex film-coated tablets debossed with 'L27' on one side and plain on the other side.

Delofine XL 10 mg Prolonged-Release Tablets are white circular, biconvex film-coated tablets debossed with 'L28' on one side and plain on the other side.

The tablets are packaged in PVC/PE/PVDC-aluminium blister in packs of 14, 20, 28, 30, 50, 90, 98 and 100 tablets are available.

Not all pack sizes may be marketed.

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For information in large print, tape, CD or Braille, please contact medical enquiries on 0116 478 0322.

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