

## Package leaflet: Information for the patient

**Felodipine 2.5 mg prolonged-release tablets**  
**Felodipine 5 mg prolonged-release tablets**  
**Felodipine 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. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Felodipine is and what it is used for
2. What you need to know before you take Felodipine
3. How to take Felodipine
4. Possible side effects
5. How to store Felodipine
6. Contents of the pack and other information

#### 1. What Felodipine is and what it is used for

Felodipine contains 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.

Felodipine 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 Felodipine

##### Do not take Felodipine:

- 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

Felodipine, 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 Felodipine, especially if you have problems with your liver.

Taking Felodipine 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 Felodipine is not recommended in children.

##### Other medicines and Felodipine

Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines/herbal remedies can affect treatment with Felodipine.

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 infection, 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 Felodipine and should therefore be avoided.

##### Felodipine with food and drink

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

##### Pregnancy and breast-feeding

###### Pregnancy

**Do not use Felodipine if you are pregnant.**

###### Breast-feeding

**Tell your doctor** if you are breast-feeding or about to start breast-feeding. Felodipine 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

Folpik 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.

##### Felodipine contains lactose

Felodipine contains 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 medicinal product.

#### 3. How to take Felodipine

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Felodipine extended 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 Felodipine than you should**

If you take more than the recommended number of doses of Felodipine, 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 Felodipine**

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 Felodipine**

If you stop taking this medicine your condition may return. Please consult your doctor and seek advice before you stop taking Felodipine. 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 any of the following happen to you, stop taking Felodipine and tell a doctor straight away:

- Hypersensitivity and allergic reactions: The signs may include raised lumps on your skin (wheals) 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 Felodipine, check with your doctor right away.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor. 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](http://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 Felodipine**

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not use this medicine if you notice the packaging is torn or damaged.

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 Felodipine contains:**

The active substance is felodipine.

Each tablet contains 2.5mg, 5mg or 10 mg of felodipine.

##### **The other ingredients are:**

- microcrystalline cellulose
  - lactose monohydrate
  - hypromellose
  - povidone K25
  - propyl gallate (Ph.Eur.)
  - colloidal anhydrous silica
  - magnesium stearate (Ph.Eur.)
  - talc
  - propylene glycol
  - iron oxide yellow (E 172)
  - titanium dioxide (E 171)
- In addition the 5 and 10 mg tablets contain:
- iron oxide red (E 172)

##### **What Felodipine looks like and contents of the pack:**

Felodipine tablets are round and film-coated.

Felodipine 2.5mg are yellow, 5mg are light pink, and 10mg are reddish brown.

They are available in blister packs containing 10, 20, 28, 30, 30 x 1, 50, 50 x 1, 98, 100, 100 x 1 and 250 prolonged release tablets.

They are available in bottle packs containing 100, 250 prolonged release tablets.

Not all pack sizes may be marketed.

##### **Marketing Authorisation Holder and Manufacturer:**

###### **Marketing Authorization Holder:**

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

###### **Manufacturer:**

Merckle GmbH, Ludwig-Merckle-Straße 3, 89143 Blaubeuren, Germany

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