

FELOCOR[®] modified release tablet

Active Ingredient (Felodipine 5 mg and 10 mg)

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What Felocor is used for

Felocor contains the active ingredient *Felodipine*.

Felocor is used to treat high blood pressure (hypertension) and stable angina pectoris (chest pain).

How Felocor works

Felodipine belongs to the group of medicines called Calcium Channel Blockers. It lowers blood pressure by expanding the small blood vessels allowing the blood to be pumped around the body more easily.

The modified-release tablet formulation of Felocor means that the tablets are designed to work over a 24-hour period.

Before you use Felocor

- When you must not use it

Do not take Felocor if you:

- Have ever had allergic reaction to the active ingredient felodipine (or other medicines in the dihydropyridine group such as amlodipine or nifedipine), or to any other ingredients in Felocor,
- Have any heart valvular problems or any other heart condition that obstructs blood flow to the body
- Have cardiogenic shock (a serious condition where the heart is damaged and unable to supply enough blood to the body),
- Have unstable angina pectoris which causes unexpected heart pain that occurs during rest.
- Have decompensated heart failure (heart has lost the ability to supply enough blood to the body)
- Have had a heart attack in the last 2 month.

- Pregnancy and lactation

- Do not use Felocor if you are pregnant, trying to get pregnant or think you may be pregnant. Felocor is not recommended during pregnancy and may cause harm to the baby.
- Do not use Felocor if you are breastfeeding. Felocor is not recommended for mothers who are breastfeeding. Your doctor may choose another treatment for you if you wish to breastfeed.

If you are not sure whether you should start taking this medicine, consult your doctor

- If you are lactose intolerant or have a disease that makes you lactose intolerant such as rare hereditary galactose intolerance and Lapp Lactose deficiency or glucose

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes
Tell your doctor if you:

- Think you are (or might be) pregnant,
- Have a history of swelling of the face, lips, tongue, throat, hands or feet due to allergy.
- Have any heart problem, including chest pain,
- Suffer from any kidney problems
- Suffer from any liver problems,
- Suffer from inflammation of gums.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Cimetidine – a medicines used to treat stomach ulcers or heartburn.
- Anti HIV / protease inhibitors - ritonavir
- Grape fruit juice,
- Medicines to treat depression (eg. Amitriptyline and clomipramine),
- Medicines for fungal infections (eg. ketoconazole, itraconazole),
- Erythromycin – an antibiotic,

- Medicines for epilepsy or convulsions (eg. carbamazepine, phenytoin, phenobarbital),
- Cyclosporine – a medicine given to prevent your body from rejecting the transplanted organ,
- Tacrolimus
- Rifampicin
- Barbiturates
- Efaviren
- Nevirapine
- Hypericum perforatum (St John Wartz)
- Warfarin

Your doctor or pharmacist will have more information on the medicines you should avoid.

How to use Felocor

- How much to use

Always take Felocor exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

The dose given by your doctor may differ from the information in this leaflet.

The usual starting dose is 5mg once daily. Depending on your response, your doctor may increase your Felocor dose. The recommended initial dose should be adjusted in the elderly and patient with impaired liver function. Caution should be taken in patients with severe renal impairment.

Felocor tablets may also be given together with other blood pressure lowering medicines.

Disease Conditions	Dosage recommended
Hypertension	5 mg once daily, the dose may be further increased according to demand. The usual maintaining dose is between 5 mg to 10 mg once daily. Initial treatment for elderly patients is 2.5 mg.

Angina Pectoris	5 mg once daily, the dose may be further increased according to demand. The usual maintaining dose is between 5 mg to 10 mg once daily.
Liver or Kidney Impairment	Please consult your doctor
Pediatric Population	Should not be used in children

- When to use it

Take Felacor at the same time everyday to ensure good control on your blood pressure.

- How long to use it

Continue to take your medicines as long as your doctor recommends. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

Do not take a double dose to make up for the dose you missed.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the carton or any remaining tablets you have with you.

Taking too many tablets may cause headache, nausea, dizziness, fainting, or easy fatigability

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do

- Take the medicine as a whole with plenty of water.

- This medicine must be taken with a light meal
- Always take Felacor exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicine, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, if the side effects worsens or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking Felacor, tell your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Felacor.

- Things you must not do

- Do not take grapefruit juice with Felacor as it may increase the effect of the drug.
- Do not crush or chew the medication.
- Do not take Felacor after consuming a meal high in fat content.
- Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.
- Do not use Felacor after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

• Driving and using machines

Be careful when driving or operating machineries while you are taking Felacor. Felacor may cause dizziness or drowsiness in some people especially during the first dose or after the dose is increased. If you experience dizziness or drowsiness, consult your doctor before attempting such activities.

Drinking alcohol after consuming Felacor may also cause drowsiness and dizziness

Side effects

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

Visit your doctor or pharmacist immediately if you notice the following side effects:

- Flushing (reddening of the face)
- Headache
- Awareness of fast heart rate (Palpitations)
- Dizziness
- Fatigue
- Tinnitus (ringing or buzzing noise)
- Swelling of ankles or hands (edema)
- Tremors and numbness or tingling sensation
- Fainting
- Nausea
- Abdominal Pain
- Vomiting
- Gum swelling and redness
- Altered liver profile of blood test results
- Low blood pressure
- Rash and itch
- Joint and muscle pain
- Frequent urination
- Impotence
- Fever
- Swelling of throat that leads to difficulty in breathing
- Weight gain
- Sweating

These effects are more likely to occur if you are taking high dosage. They usually occur during the start of the treatment or when the dose is increased. They usually decrease in intensity of cease with time.

The following are serious but rare side effects. You may need urgent medical attention.

• Severe allergic reaction that manifest as breathing difficulty accompanied by rash, itching, swelling of hands, face, lips or tongue

Tell your doctor or pharmacist immediately if you notice the side effects continues or getting serious or anything else that make you feel unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public -> Reporting Side Effects to Medicines(ConSERF) or Vaccines (AEFI))

Storage and Disposal of Felocor

Storage

Store in a cool dry place below 30°C. Store in original package to protect from heat and moisture.

Do not store Felocor or any other medicines in the bathroom, near a sink, leave it at the window sill or in the car.

Keep out of the reach and sight of children.

- Disposal

The expiry date of Felocor is printed on the carton and blister. Do not use if after expiry date.

If your doctors tell you to stop taking Felocor or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

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.

Product Description

- What it looks like

What it looks like?

Felocor® 5mg modified-release tablet is a round, biconvex film-coated, pale-red to grey-red tablet embossed with the 'F5' on one side.

Felocor® 10mg modified-release tablet is a round, biconvex film-coated, pale-red to grey-red tablet embossed with the 'F10' on one side.

Felocor comes in strip packs of 30, 50, or 100 modified-release tablets per box.

- Ingredients

- Active ingredient

Felocor® 5mg: *Felodipine* 5mg

Felocor® 10mg: *Felodipine* 10mg

- Inactive ingredients

Lactose monohydrate, hydroxypropyl methylcellulose, sodium lauryl sulphate, microcrystalline cellulose, magnesium stearate, ferric oxide (yellow), ferric oxide (red), opadry white (consist of lactose monohydrate, macrogol, titanium dioxide, hydroxypropylmethylcellulose).

- MAL Number

Felocor® 5mg: MAL07050185AZ

Felocor® 10mg: MAL07050186AZ

Manufacturer

Manufactured by:

Salutas Pharma GmbH

Otto-von-Guericke-Allee 1, D-39179

Barleben, Germany

For:

HEXAL AG

Industriestraße 25,

83607 Holzkirchen, Germany

Product Registration Holder

Marketing Authorisation Holder:

Idaman Pharma Sdn. Bhd.

17, Jalan Wangsa Delima 1A,

Seksyen 5, Pusat Bandar Wangsa Maju,

53300 Kuala Lumpur, Malaysia

Authorised Importer and Distributor:

IMEKS Pharma Sdn. Bhd.

5&9, Jalan Udang Harimau 2,

Medan Niaga Kepong

51200 Kuala Lumpur, Malaysia

Date of revision

27 September 2018

Serial Number

(It will be given during evaluation)