

Felodin Tab. 5mg

(Felodipine 5mg)

■ COMPOSITION

Each tablet contains Felodipine 5mg.

■ INDICATION

Hypertension and prophylaxis of chronic stable angina pectoris

■ DOSAGE & ADMINISTRATION

Felodin tablets must not be chewed or crushed. They should be swallowed whole with half a glass of water.

• Hypertension

Adults (including elderly) The dose should be adjusted to the individual requirements of the patient. The recommended starting dose is 5mg once daily. If necessary, dose may be further increased or another antihypertensive agent added.

The usual maintenance dose is 5-10 mg once daily. Doses higher than 20mg daily are not usually needed. For dose titration purposes a 2.5mg tablet is available. In elderly patients an initial treatment 2.5mg daily should be considered.

• Angina pectoris

Adults The dose should be adjusted individually. Treatment should be started with 5mg once daily and if needed be increased to 10mg once daily.

Children The safety and efficacy of Felodin in children has not been established. Felodin can be used in combination with β -blockers, ACE inhibitors or diuretics. The effects on blood pressure are likely to be additive and combination therapy will usually enhance the antihypertensive effect. Care should be taken to avoid hypotension.

In patients with severely impaired liver function the dose of Felodin should be low. The pharmacokinetics are not significantly affected in patients with impaired renal function.

■ PRECAUTION

1. Contraindication

- Pregnancy
- As with other calcium channel blockers, Felodin should be discontinued in patients who develop cardiogenic shock.
- Patient with a previous allergic reaction to Felodin.
- Felodin should not be used in patients with clinically significant aortic stenosis, uncompensated heart failure, and during or within one month of a myocardial infarction.
- Unstable angina pectoris
- In patients with severely impaired liver function

2. General Precaution

As with other vasodilators, Felodin may, in rare cases, precipitate significant hypotension with tachycardia which in susceptible individuals may result in myocardial ischaemia.

There is no evidence that Felodin is useful for secondary prevention of myocardial infarction.

The efficacy and safety of Felodin in the treatment of malignant hypertension has not been studied.

Felodin should be used with caution in patients with severe left ventricular dysfunction.

3. Adverse reaction

As with other calcium antagonists, flushing, headache, palpitations, dizziness and fatigue may occur. These reactions are usually transient and are most likely to occur at the start of treatment or after an increase in dosage.

- As with other calcium antagonists ankle swelling, resulting from precapillary vasodilation, may occur. The degree of ankle swelling is dose related.
- In patients with gingivitis/periodontitis, mild gingival enlargement has been reported with Felodin, as with other calcium antagonists. The enlargement can be avoided or reversed by careful dental hygiene.
- As with other dihydropyridines, aggravation of angina has been reported in a small number of individuals especially after starting treatment. This is more likely to happen in patients with symptomatic ischaemic heart disease.

The following adverse events have been reported from clinical trials and from Post Marketing Surveillance. In the great majority of cases a causal relationship between these events and treatment with felodin has not been established.

Skin : very rarely - leucocytoclastic vasculitis, rarely - rash and/or pruritus, and

isolated cases of photosensitivity

Musculoskeletal : in isolated cases arthralgia and myalgia

Psychiatric : rarely impotence/sexual dysfunction

Central and peripheral nervous system : headache, dizziness. In isolated cases paraesthesia

Gastrointestinal : very rarely - gingivitis, in isolated cases abdominal pain, nausea, vomiting, gum hyperplasia

Hepatic : in isolated cases increased liver enzymes

Urinary system : very rarely urinary frequency

Cardiovascular : rarely - tachycardia, palpitations and syncope

Vascular (extracardiac) : peripheral oedema, flush

Other : very rarely - fever, rarely - fatigue, in isolated cases hypersensitivity reactions e.g. urticaria, angio-oedema

4. Special caution in the use

As with other vasodilators, Felodin may, in rare cases, precipitate significant hypotension with tachycardia which in susceptible individuals may result in myocardial ischaemia.

There is no evidence that Felodin is useful for secondary prevention of myocardial infarction.

The efficacy and safety of Felodin in the treatment of malignant hypertension has not been studied.

Felodin should be used with caution in patients with severe left ventricular dysfunction

5. Drug interaction

- Concomitant administration of substances which interfere with the cytochrome P4503A4 enzyme system may affect plasma concentrations of Felodin.

Enzyme inhibitors such as cimetidine, erythromycin, itraconazole and keto conazole impair the elimination of Felodin, and Felodin dosage may need to be reduced when drugs are given concomitantly.

- Conversely, powerful enzyme inducing agents such as some anticonvulsants (phenytoin, carbamazepine, phenobarbitone) can increase Felodin elimination and higher than normal Felodin doses may be required in patients taking the drugs.

- When used concomitantly, Felodin may increase the concentration of digoxin.

- Felodin does not appear to affect the unbound fraction of other extensively plasma protein bound drugs such as warfarin.

- Grapefruit juice results in increased peak plasma levels and bioavailability possibly due to an interaction with flavonoids in the fruit juice. This interaction has been seen with other dihydropyridine calcium antagonists and represents a class effect. Therefore grapefruit juice should not be taken together with Felodin.

- When used concomitantly, Felodin may increase the concentration of metoprolol

6. Pregnancy and lactation

Felodin should not be given during pregnancy.

In a study on fertility and general reproductive performance in rats, a prolongation of parturition resulting in difficult labour, increased foetal deaths and early postnatal deaths were observed in the medium-and high-dose groups.

Reproductive studies in rabbits have shown a dose-related reversible enlargement of the mammary glands of the parent animals and dose-related digital abnormalities in the foetuses when Felodin was administered during stages of early fetal development.

Felodin has been detected in breast milk, but it is unknown whether it has harmful effects on the new-born.

■ **STORAGE :** Store at 1 - 30°C in air tight containers.

■ **SHELF LIFE :** 3 Years

■ **PACKAGE :** 20 Tablets /Box

※ Keep medicines out of reach of children.

This drug is manufactured in accordance with Korea Good Manufacturing Practice (KGMP) as recommended by WHO