

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
Pinefeld XL 10mg Prolonged-Release Film-Coated 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 further questions, ask your doctor or your 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 Pinefeld is and what it is used for
2. What you need to know before you take Pinefeld
3. How to take Pinefeld
4. Possible side effects
5. How to store Pinefeld
6. Contents of the pack and other information

1. What Pinefeld is and what it is used for

The active ingredient in Pinefeld XL is **felodipine** which belongs to a group of medicines called calcium channel blockers. These work by blocking the effects of calcium on the blood vessels (narrowing of the blood vessels) which helps the blood vessels to relax and widen, increasing the blood flow and supply of oxygen to the heart, reducing the heart's workload.

Pinefeld is used to treat the following:

- High blood pressure (hypertension)
- To prevent angina (chest pain)

The name of this medicine is Pinefeld XL 10mg Prolonged-Release Film-Coated Tablets (felodipine) and is referred to as **Pinefeld** throughout this leaflet.

2. What you need to know before you take Pinefeld

Do not take Pinefeld if:

- You are allergic to felodipine, other calcium channel blockers or any of the other ingredients of this medicine (listed in section 6)
- You suffer from an insufficient blood supply to the heart muscle which can cause chest pain (unstable angina pectoris)
- You have had a severe heart attack within the last month (acute myocardial infarction)
- You suffer from heart failure or heart disease
- You are pregnant, think you may be pregnant or are planning to have a baby (see "Pregnancy and breastfeeding" section)

Warnings and precautions

Talk to your doctor before taking Pinefeld:

- If you suffer from heart problems such as:
 - Low blood pressure (hypotension)
 - Faster heartbeat (tachycardia)
 - Reduced blood flow to the heart muscle by a partial or complete blockage of the arteries (myocardial ischaemia)
- If you suffer from liver disorders
- If you suffer from swelling of the gums (gingivitis) or a serious gum infection that damages the soft tissue and destroys the bone that supports the teeth (periodontitis). Mild enlargement of the gums can be avoided or reversed by careful dental hygiene.

Other medicines and Pinefeld

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Pinefeld:

- Medicines used to treat stomach ulcers such as cimetidine (H2-receptor antagonists)
- Medicines used to treat fungal infections such as itraconazole, ketoconazole (azole antifungals)
- Medicines used to treat bacterial infections such as erythromycin, rifampicin (antibiotics)
- Medicines used to treat HIV infection (HIV protease inhibitors) such as ritonavir and efavirenz, nevirapine (Non-Nucleoside Reverse Transcriptase Inhibitors [NNRTIs])
- Medicines used to control seizures and epilepsy such as carbamazepine, phenytoin (anticonvulsant)
- St John's Wort, a herbal remedy used to treat depression
- Medicines used to treat anxiety and sleep disorders such as phenobarbital (barbiturates)
- Medicines used to reduce the body's immunity when receiving organ transplant such as tacrolimus (immunosuppressants)

Taking Pinefeld with food and drink

- During treatment with Pinefeld, a low-fat, low-carbohydrate diet should be followed.
- These tablets may be taken with or without food.
- **Grapefruit juice** should be **avoided** during treatment with Pinefeld. Grapefruit juice can affect the amount of felodipine (the active ingredient in Pinefeld) in the blood.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, Pinefeld **must not** be taken.

Breast feeding

If you are breast-feeding, Pinefeld should **not** be taken as felodipine (the active ingredient in Pinefeld) is passed into breast milk.

Driving and using machines

Pinefeld may cause headache, feeling sick (nausea), dizziness or tiredness (fatigue). This is more likely to occur at the start of treatment. If any of these symptoms are experienced, it may be necessary to avoid driving or operating machinery.

Pinefeld contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Information about the sodium content of Pinefeld

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Pinefeld

Always take Pinefeld exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- These tablets are to be taken orally, in the morning, with water.
- These tablets should be swallowed whole. Do **not** break, chew or crush these tablets because they will be absorbed into the body too quickly.
- During treatment with Pinefeld, a low-fat, low-carbohydrate diet should be followed.
- These tablets may be taken with or without food.
- **Grapefruit juice** should be **avoided** during treatment with Pinefeld. Grapefruit juice can affect the amount of felodipine (the active ingredient in Pinefeld) in the blood.

Adults

- The recommended starting dose is 5mg once daily.
- The standard maintenance dose is 5-10mg once daily.
- Doses higher than 20mg daily are not usually required.
- Depending on the therapeutic response, the dose can be **decreased** to 2.5mg if applicable.
- Depending on the therapeutic response, the dose can be **increased** to 10mg once daily
- Another antihypertensive medicine may be added if necessary.
- Dose increases should occur at intervals of at least 2 weeks.

Elderly

Treatment should be started with the lowest available dose.

Patients with kidney disorders

- Dose adjustment is not required for patients with impaired kidney function.
- Caution should be taken in patients with **severely** impaired kidney function.

Patients with liver disorders

- Patients with impaired liver function may have increased concentrations of felodipine (the active ingredient in Pinefeld) in their blood and may require a lower dose.
- In patients with mild to moderately impaired liver function, the recommended starting dose should be the lowest minimum dose of Pinefeld.
- The dose should only be increased after balancing the benefits against the risks.
- Pinefeld should **not** be used in patients with **severely** impaired liver function.

Use in children

Pinefeld Tablets are **not** recommended for children.

If you take more Pinefeld than you should:

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. **The symptoms of overdose are;** excessive widening of the veins and arteries of the outer parts of the body (peripheral vasodilatation) with low blood pressure (hypotension) and rarely a slower heartbeat (bradycardia).

If you forget to take Pinefeld

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose **do not** take a double dose to make up for a forgotten dose.

If you stop taking Pinefeld

- It is important that you keep taking Pinefeld for as long as your doctor has told you to.
- If treatment with Pinefeld is stopped abruptly, a hypertensive crisis (severe increase in blood pressure that may cause irreversible organ damage and/or stroke) may occur.

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

4. Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Swelling of parts of the body (peripheral oedema)

Common side effects (may affect up to 1 in 10 people)

- Headache. This is usually only temporary and appears at the start of treatment or following a dose increase
- Reddening of the face (flushing). This is usually only temporary and appears at the start of treatment or following a dose increase

Uncommon side effects (may affect up to 1 in 100 people)

- Dizziness. This is usually only temporary and appears at the start of treatment or following a dose increase
- Tingling or numbness in the hands or feet (paraesthesia)
- Low blood pressure (hypotension)
- Faster heartbeat (tachycardia)
- Feeling your heartbeat (palpitations)
- Stomach pain
- Feeling sick (nausea)
- Skin rashes
- Severe itching (pruritis)
- Tiredness, weakness or lack energy (fatigue). This is usually only temporary and appears at the start of treatment or following a dose increase

Rare side effects (may affect up to 1 in 1000 people)

- Fainting (syncope)
- Inability to have or maintain an erection (impotence) or sexual problems
- Skin rashes with the formation of wheals (urticaria)
- Being sick (vomiting)
- Muscle pain (myalgia)
- Pain or swelling in the joints (arthralgia)

Very rare side effects (may affect up to 1 in 10,000 people)

- Swelling/inflammation of gums [gingival hyperplasia/gingivitis] (can be prevented/reversed by careful dental hygiene)
- Liver function disorders (detected by blood tests)
- Frequent need to urinate (pollakisuria)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Inflammation of the blood vessels (leukococlastic vasculitis)

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 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 Pinefeld

- Keep this medicine out of the sight and reach of children.
- Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- 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 Pinefeld contains:**

Each prolonged-released film-coated tablet contains 10mg of felodipine.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, sodium laurilsulfate, hypromellose, magnesium stearate, macrogol 4000, iron oxide (E172) and titanium dioxide (E171).

What Pinefeld looks like and contents of the pack:

Pinefeld are grey-red, round, biconvex, prolonged-release, film-coated tablets with an approximate diameter of 9mm, with the imprint F10 on one side.

Pinefeld is available in:

Pinefeld Tablets are available in packs of 7, 14, 28 or 98 tablets.

Not all pack sizes may be marketed.

Product Licence Number:

PL 11311/0342

Marketing Authorisation Holder:

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
United Kingdom

Manufacturer:

Kleva Pharmaceuticals S.A.
189, Parnithos AVE.
136 75 Acharnai - Attiki
Greece

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