

Package leaflet: Information for the patient

Calcifediol Faes 72 micrograms soft capsules calcifediol

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Calcifediol Faes is and what it is used for
2. Before you need to know before you take Calcifediol Faes
3. How to take Calcifediol Faes
4. Possible side effects
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1. What Calcifediol Faes is and what it is used for

It contains a form of vitamin D, calcifediol, which is used to prevent and treat vitamin D deficiency and derived problems. Vitamin D is involved in the human body, among other actions, it increases the calcium absorption.

Calcifediol Faes is used to treat vitamin D deficiency in adults and to prevent vitamin D deficiency in adults with identified risks.

Calcifediol Faes is also used to treat certain bone conditions, such as thinning of the bone (osteoporosis) in adults.

2. Before you need to know before you take Calcifediol Faes

Do not take Calcifediol Faes:

- If you are allergic to calcifediol or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from hypercalcaemia (high levels of calcium in the blood) or hypercalciuria (high levels of calcium in the urine).
- If you suffer from calcium stones formation.
- If you have been diagnosed with hypervitaminosis D (excess of vitamin D in the organism).

Warnings and precautions

Talk to your doctor or pharmacists before taking Calcifediol Faes.

- You should not exceed the recommended daily intake of vitamin D supplements, like this medicine, because it may result in poisoning (see section 3, paragraph *If you take more Calcifediol Faes than you should*).
- While you are taking this medicine or before you start, your doctor may tell you to take blood or urine tests to check levels of calcium, phosphorus and other parameters.

- Patients with kidney disease require special care and must be specially monitored by the doctor, conducting regular analysis.
- Patients with heart disease require special care and must be frequently monitored by the doctor to control blood calcium, especially those receiving treatment with cardiac glycosides (see in this section, paragraph *Taking Calcifediol Faes with other drugs*).
- If you have hypoparathyroidism (insufficient function of the parathyroid hormone) this drug may be less active.
- If you have a tendency to get calcium-containing kidney stones, your doctor should monitor your blood calcium levels.
- Patients with prolonged immobilization may need lower doses of this medication.
- Patients with sarcoidosis (disease with nodules, usually on the skin), tuberculosis or other diseases with nodules should be especially careful with this medication, as they have more risk of side effects at lower doses than the recommended ones. Periodic analyses should be performed to control the levels of calcium in blood and urine.
- Interference with laboratory tests: If you are going to have any diagnostic test done (including blood, urine, skin tests using allergen, etc.) inform the doctor that you are taking this medication because it may influence the results. For example, in a cholesterol test.

Children and adolescents

The use of Calcifediol Faes is not indicated in children and adolescents.

Other medicines and Calcifediol Faes

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can alter the way this medicine works. On the other hand, Calcifediol Faes or its active ingredient calcifediol monohydrate can affect the effectiveness of other drugs taken simultaneously.

Therefore, they may interact with the following drugs:

- Medicines used to treat epilepsy (such as phenytoin, phenobarbital and primidone) and other enzyme-inducing drugs (favouring the reduction of Calcifediol Faes effect).
- Heart medicines and/or hypertension and cardiac glycosides, thiazide diuretics or verapamil.
- Cholestyramine, colestipol (for cholesterol), orlistat (for obesity). Intake of these drugs and calcifediol monohydrate should be separated at least 2 hours.
- Mineral oil or paraffin (laxatives): Using another type of laxative or separating intake of both drugs is recommended.
- Some antibiotics (such as penicillin, rifampicin, isoniazide, neomycin and chloramphenicol).
- Magnesium salts.
- Other products with Vitamin D.
- Calcium supplements.
- Corticosteroids (anti-inflammatory drugs).
- Verapamil (anti-hypertensive drug).
- Medicines that inhibit cytochrome P-450 (e.g. atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole)

Calcifediol Faes with food and drinks

Some foods and drinks are supplemented with vitamin D. This should be taken into account since the effects could be added to the effects of this medicine and therefore be excessive.

Pregnancy, breast-feeding and fertility

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.

This medicinal product is not recommended during pregnancy and breast-feeding. Calcifediol passes into breast milk. This should be taken into account when additional vitamin D is administered to the infant.

There are no data on the effects of calcifediol on fertility.

Driving and using machines

Calcifediol Faes has no or negligible influence on the ability to drive and use machines.

Calcifediol Faes contains ethanol, sorbitol liquid (non crystallising) (E 420) and Allura red (E 129).

This medicine contains 1 mg of alcohol (ethanol) in each soft capsule. The amount in one capsule of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 10 mg of sorbitol as sorbitol liquid (non-crystallising) in each soft capsule, which is equivalent to 0.04 mg/mg.

This medicine contains Allura red (E 129) which may cause allergic reactions.

3. How to take Calcifediol Faes

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

Recommended doses are as follows:

- Treatment of vitamin D deficiency and prevention of vitamin D deficiency in patients with identified risks: one capsule once a week.
- Addition to specific therapy for osteoporosis: one capsule once a week.

This medicine should not be administered with a daily frequency.

Your doctor should monitor your calcium and vitamin D levels periodically, usually before starting the treatment and after 3-4 months.

For oral use.

Calcifediol Faes can be administered with or without a meal, swallowed whole and could be taken with water, milk or juice.

If you take more Calcifediol Faes than you should

If you take more of this medicine than the dose prescribed by your doctor (overdose) and/or for a long time, hypercalcemia (high blood calcium levels) and phosphates in urine and blood may appear, possibly leading to kidney failure. Some symptoms of toxicity can appear early and others later on. Initial symptoms include: weakness, fatigue, headache, loss of appetite, dry mouth, digestive disorders such as vomiting, abdominal cramps, constipation or diarrhoea, increased thirst; increased urination, muscle pain. Some symptoms that may occur later are: itching, weight loss, stunted growth in children, kidney disorders, intolerance to sunlight, conjunctivitis, increased cholesterol, transaminases, inflammation of the pancreas, calcification (calcium salts deposits) in blood vessels and other tissues such as tendons and muscles, increased blood pressure, mental disorders, irregular heartbeat. The symptoms of overdose usually improve or disappear when treatment is stopped, but if intoxication is severe kidney or heart failure can occur.

If you forget to take Calcifediol Faes

Do not take a double dose to make up for a forgotten capsule.

Take the missed dose as soon as possible; then back to your regular dosing schedule.

If you stop taking Calcifediol Faes

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

4. Possible side effects

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

Adverse effects can occur in case of excessive or more prolonged treatment than prescribed by your doctor, which may cause hypercalcemia (increased levels of calcium in blood), and hypercalciuria (increased calcium levels in urine), see section 3 for description of symptoms.

Other adverse effects include allergic reactions such itching, local swelling, difficulty in breathing and skin redness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPR A Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Calcifediol Faes

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.

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 protect the environment

6. Contents of the pack and further information

What Calcifediol Faes contains

- The active substance is calcifediol. Each capsule contains 72 micrograms of calcifediol as calcifediol monohydrate.
- The other ingredients are: anhydrous ethanol, medium chain triglycerides and the components of the capsule include: gelatin, glycerol, sorbitol liquid (non-crystallising) (E 420), titanium dioxide (E 171) and Allura red (E 129).

What Calcifediol Faes looks like and content of the pack

Calcifediol Faes are pink, oval soft gelatin capsules with a longitudinal joint. The capsules are packed in PVC/PVDC//Alu blisters containing 4, 12, 16, 24 or 48 capsules. Blisters are packed in a cardboard box.

Marketing Authorisation Holder and Manufacturer

Faes Farma, S.A.
C/ Máximo Aguirre, 14
Leioa,
48940 Bizkaia

Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Spain: Hidroferol semanal 75 microgramos cápsulas blandas

Portugal: Dvit semanal 75 microgramas cápsula mole

Finland: Defevix 72 mikrogrammaa kapseli, pehmeä

Sweden: Defevix veckokapsel 72 mikrogram kapsel, mjuk

Norway: Defevix

Greece: D Ready

Netherlands: Dediol wekelijks 72 microgram zachte capsules

Italy: Neodiset

Belgium: Hidroferol Hebdomadaire 75 microgrammes capsules molles

Luxembourg: Hidroferol Hebdomadaire

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