

HIDROFEROL 0.266mg Soft Capsules

Calcifediol monohydrate

What is in this leaflet

1. What Hidroferol 0.266mg Soft Capsules is used for
2. How Hidroferol 0.266mg Soft Capsules works
3. Before you use Hidroferol 0.266mg Soft Capsules
4. How to use Hidroferol 0.266mg Soft Capsules
5. While you are using it
6. Side effects
7. Storage and Disposal of Hidroferol 0.266mg Soft Capsules
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Hidroferol 0.266mg Soft Capsules is used for?

Hidroferol 0.266mg Soft Capsules contains Calcifediol monohydrate as the active ingredient.

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

Hidroferol 0.266 mg soft capsules is used to treat vitamin D deficiency in adults and to prevent vitamin D deficiency in adults with identified risks such as in patients with malabsorption syndrome, chronic kidney disease mineral and bone disorder (CKD-MBD) or other identified risks.

Hidroferol 0.266 mg soft capsules is also used to treat thinning of the bone (osteoporosis), as supplement of other medicines in patients with vitamin D deficiency or at risk of vitamin D deficiency

How Hidroferol 0.266mg Soft Capsules works

Vitamin D increases absorption

of calcium and phosphorus in the intestine and improves normal bone formation and mineralization

Before you use Hidroferol 0.266mg Soft Capsules

When you must not use it

Do not take Hidroferol

0.266mg Soft Capsules :

- If you are allergic (hypersensitive) to Calcifediol, or to any of the ingredients.
- If you suffer from hypercalcaemia (high levels of calcium in the blood) or hypercalciuria (high calcium levels 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).

Before you start to use it

Always tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not exceed the recommended daily intake of vitamin D supplements, like this medicine, because it may result in poisoning (see section 'Taking other medicines').

- 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, 'If you use too much (overdose)').
- 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.
- Your doctor must inform you and your family and/or caregivers of the importance of taking the drug at the doses indicated by him/her and of recommendations about your diet and calcium supplements intake to avoid overdosing.
- Interference with laboratory tests: If you are going to have any diagnostic test done (including blood, urine, skin tests using allergen,

HIDROFEROL 0.266mg Soft Capsules

Calcifediol monohydrate

etc) inform the doctor that you are taking this medication because it may influence the results. For example, in a cholesterol test.

This medicine contains 4.98 mg of alcohol (ethanol) in each capsule. The amount in 1 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 22 mg of sorbitol in each capsule. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine may cause allergic reactions because it contains sunset yellow (E-110). It can cause asthma, especially in patients allergic to acetylsalicylic acid.

Children and adolescents

The efficacy and safety of Hidroferol 0.266 mg soft capsules have not been established in the paediatric population. Use of this product is not recommended in the paediatric population.

Hidroferol 0.266 mg soft capsules with food and drinks

Some 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 & Lactation

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.

Do not take this medicine during pregnancy.

Do not take this medicine while breastfeeding your baby.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines can alter the way this medicine work. On the other hand, Hidroferol 0.266 mg soft capsules or calcifediol, its active ingredient 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 (favoring the reduction of Hidroferol 0.266mg soft capsules 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 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, neomycin and chloramphenicol).

- Magnesium salts.
- Other products with Vitamin D.
- Calcium supplements.
- Corticosteroids (anti-inflammatory drugs).

How to use Hidroferol 0.266mg Soft Capsules

How much to use

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

Do not take more medicine or more often than what has been prescribed (weekly, biweekly or monthly). If you do, the risk of overdose increases.

Recommended doses are as follows:

Treatment of vitamin D deficiency and prevention of vitamin D deficiency in patients with identified risks: one capsule (0.266 mg of calcifediol) once a month.

Addition to specific therapy for osteoporosis : one capsule once a month

There are populations at high risk of vitamin D deficiency which may need to take higher doses, after analytical verification of the extent of the deficiency, the doctor may consider a dose of one capsule every two weeks or every week. This medicine should not be administered with a daily frequency.

Your doctor will need to check your calcium and vitamin D levels regularly, usually before you start treatment and 3-4

HIDROFEROL 0.266mg Soft Capsules

Calcifediol monohydrate

months after starting treatment. Depending on the indication, doses will be reduced or spaced further apart when symptoms improve, or vitamin D deficiency is corrected.

When to use it

The recommended dose for adult is one capsule (0.266 mg of calcifediol) once a month.

How long to use it

Do not take more medicine or more often than prescribed by your doctor.

If you forget to use it

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 use too much (overdose)

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 diarrhea, increased thirst; increased urination, muscle pain. Some symptoms that may occur later on 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.

While you are using it

Things you must do

- Use your medicine exactly as your doctor has told you.

Things you must not do

- Do not give Hidroferol 0.266mg Soft Capsules to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines
Hidroferol 0.266 mg soft capsules has no or negligible influence on the ability to drive and use machines

Side effects

Like all medicines, Hidroferol 0.266mg Soft Capsules 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). Other adverse effects include allergic reactions such as itching, local swelling, difficulty in breathing and skin redness.

Tell your doctor or pharmacist if you experience any other reaction different from those described.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Hidroferol 0.266mg Soft Capsules S

Storage

Store below 30°C
Keep out of reach of children.

Disposal

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

Hidroferol 0.266mg Soft Capsules are orange soft gelatine capsules containing a clear, low viscous and free from particles liquid and packed in PVC/PVDC-Al blisters.

Ingredients

Active ingredient

Calcifediol monohydrate

Inactive ingredients

anhydrous ethanol, medium chain triglycerides and the components of the capsule include: gelatin, glycerol, sorbitol (E-420), titanium

HIDROFEROL 0.266mg Soft Capsules

Calcifediol monohydrate

dioxide (E171) and sunset
yellow (E-110).

MAL number: MAL25036004ACZ

Manufacturer

HC Clover Productos y
Servicios, S.L
C/A Alicante 8-10
Arganda del Rey
28500 Madrid
Spain

For
Faes Farma S.A
C/ Máximo Aguirre 14
48940 Leioa
Spain

Product Registration Holder

Eurodrug Laboratories (M)
Sdn Bhd
T2-21-10, The Square, One
City, Jalan USJ 25/1C, 47650
Subang Jaya Selangor Darul
Ehsan Malaysia

Date of revision

18/10/2025

Serial Number

NPRA (R1) 23/030