

Package leaflet: Information for the user

Vibosun-D3 25,000 IU capsules, soft

Cholecalciferol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Vibosun-D3 is and what it is used for
2. What you need to know before you take Vibosun-D3
3. How to take Vibosun-D3
4. Possible side effects
5. How to store Vibosun-D3
6. Contents of the pack and other information

1. What Vibosun-D3 is and what it is used for

Vibosun-D3 contains the active ingredient cholecalciferol (vitamin D3) that regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Vibosun-D3 is used to prevent and treat vitamin D deficiency in adults and adolescents (children aged ≥ 12 years).

Vibosun-D3 is also used in adults in addition to specific therapy for bone loss (osteoporosis), preferably in combination with calcium.

2. What you need to know before you take Vibosun-D3

Do not take Vibosun-D3:

- if you are allergic to cholecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- if you have kidney stones or have a tendency to form kidney stones.
- if you have severe kidney impairment.
- if you are allergic to peanut or soya.

If any of the above applies to you, talk to your doctor or pharmacist before taking Vibosun-D3.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vibosun-D3:

- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- when using other medicines containing vitamin D.
- if you have kidney problems.

Children and adolescents

This medicine is not suitable for use in children under 12 years of age.

Other medicines and Vibosun-D3

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular any of the following:

- thiazide diuretics (to treat high blood pressure).
- phenytoin or barbiturates (used to treat epilepsy).
- glucocorticoids (to treat inflammation).
- digoxin (to treat heart conditions).
- cholestyramine (used to treat high cholesterol).
- laxatives, e.g. paraffin oil
- actinomycin (chemotherapy)
- imidazole (antifungal)
- rifampicin (antibiotic)
- isoniazid (antibiotic)

Vibosun-D3 with food and drink

The capsules should be swallowed whole with water, preferably taken with a meal.

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.

Vibosun-D3 should only be used during pregnancy, if vitamin D deficiency has been clinically established.

Vibosun-D3 can be used during breastfeeding. Vitamin D3 passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

There is no data on the effect of vitamin D3 on fertility. However, normal levels of vitamin D are not expected to have any adverse effects on fertility.

Driving and using machines

Vibosun-D3 has no known effects on the ability to drive or use machines.

< PRODUCT NAME > contains lecithin from soya

< PRODUCT NAME > contains traces of lecithin from soya, which may contain soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Vibosun-D3

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

The capsules should be swallowed whole with water.

You should take this medicine preferably together with a meal to help your body absorb the vitamin D3.

Adults and adolescents

Prevention of vitamin D deficiency

The recommended dose is one capsule (25,000 IU) every 2 months to one capsule (25,000 IU) every month.

Treatment of vitamin D deficiency

For starting treatment of symptomatic vitamin D deficiency the recommended dose is one single dose of 100,000 IU (4 capsules of 25,000) or 2 doses of 50,000 IU (each consisting of 2 capsules of 25,000) taken over 1 week.

A maintenance dose of one capsule of 25,000 IU every month may be considered.

Vibosun-D3 taken in addition to specific therapy for osteoporosis in adults

The recommended dose is one capsule (25,000 IU) every month.

Medical supervision is required as the required dose may differ depending on the necessary supplementation to vitamin D and the response of the patient.

Use in children

Vibosun-D3 25,000 IU capsules are not intended for use in children under 12 years of age. Other forms of this medicine maybe more suitable for children; ask your doctor or pharmacist.

If you take more Vibosun-D3 than you should

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor, antipoisoncentre (070/245.245) or emergency unit for judgement of the risk and advice.

The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take Vibosun-D3

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

If you stop taking Vibosun-D3

Discuss with your doctor if you wish to stop taking this medicine.

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

4. Possible side effects

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

Stop taking Vibosun-D3 and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficulty swallowing
- difficulty breathing

Uncommon (may affect up to 1 in 100 people): Hypercalcaemia (increased levels of serum calcium) and hypercalciuria (increased levels of urine calcium).

Rare (may affect up to 1 in 1,000 people): Itching, rash, hives.

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 Federal Agency for Medicines and Health products - Afdeling Vigilantie - Postbus 97, 1000 BRUSSEL Madou - Website:

www.eenbijwerkingmelden.be - e-mail: adr@fagg.be. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vibosun-D3

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 the month.

Do not store above 25°C. Store in the original packaging in order to protect from moisture.

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 other information

What Vibosun-D3 contains

The active substance is cholecalciferol (vitamin D3). Each soft capsule contains 0.625 mg cholecalciferol corresponding to 25,000 IU vitamin D3.

The other ingredients are:

Capsule fill: triglycerides medium-chain, all-rac- α -Tocopherol E307,

Capsule shell: gelatin E441, glycerol E422, purified water, titanium dioxide E171, and iron oxide yellow E172. Also contains traces of triglycerides, medium-chain, lecithin/phosphatidylcholine (from soybean, see section 2 “< PRODUCT NAME > contains lecithin from soya”), caprylic/capric triglycerides, ethanol, glyceride (from sunflower seed oil), oleic acid, ascorbyl palmitate and tocopherol.

What Vibosun-D3 looks like and contents of the pack

Vibosun-D3 25,000 IU capsules are yellow, opaque, oval soft gelatin capsules with dimension of approximately 9 mm x 6 mm.

PVC/PVDC/aluminium blister, packs of 1, 2, 3 and 3x1, 4 and 4x1, 6 and 6x1, 12 and 12x1 soft capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Teva B.V., Swensweg 5, 2031 GA Haarlem, Nederland

Manufacturer

TEVA Gyógyszergyár Zrt., Pallagi út 13, 4042 Debrecen, Hongarije

Merckle GmbH, Ludwig-Merckle Strasse 3, 89143 Blaubeuren-Wuerttemberg, Duitsland

Number of marketing authorization holder

BE591635

Delivery mode

Medicine not on medical prescription.

This medicinal product is authorised in the Member States of the EEA under the following names:

BE: Vibosun-D3

HR: Plivit D3

LT: Colecalciferol Teva
NL: Cholecalciferol Teva
PL : Calsus
PT: Colecalciferol Teva
SE: Kolecalciferol Teva

This leaflet was last revised in 10/2023.