BIJSLUITER: INFORMATIE VOOR DE GEBRUIKER

Vitamine D3 Teva 25.000 IE, zachte capsules
cholecalciferol (Vitamin D3)

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 or 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 <PRODUCT NAME> is and what it is used for
2. What you need to know before you take <PRODUCT NAME>
3. How to take <PRODUCT NAME>
4. Possible side effects
5. How to store <PRODUCT NAME>
6. Contents of the pack and other information

1. What <PRODUCT NAME> is and what it is used for

<PRODUCT NAME> 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.
<PRODUCT NAME> is used for initial treatment of clinically relevant vitamin D deficiency in adults.

2. What you need to know before you take <PRODUCT NAME>

Do not take <PRODUCT NAME> if you

- are allergic to cholecalciferol or any of the other ingredients of this medicine (listed in section 6).
- have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- have kidney stones.
- have calcium deposits in your kidneys (nephrocalcinosis).
- have severe kidney impairment.
- have hypervitaminosis D (increased levels of vitamin D in the blood)
- are allergic to peanut or soya.

If any of the above applies to you, talk to your doctor or pharmacist before taking <PRODUCT NAME>.

Warnings and precautions
Talk to your doctor or pharmacist before taking <PRODUCT NAME>
- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- when using other medicines or food supplements containing vitamin D or related substances.
- if you have kidney problems.
- if you suffer from pseudohypoparathyroidism.

Your doctor might need to measure the levels of calcium in your blood or urine and to monitor your kidney (renal) function. Monitoring is especially important for elderly patients, who concomitantly take cardiac medicines (glycodsides or diuretics) and for patients with increased risk for kidney stones.

Children and adolescents
This medicine is not suitable for use in children and adolescents under 18 years of age.

Other medicines and <PRODUCT NAME>
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)
- cardiac glycosides (to treat heart conditions, e.g. digoxin)
- cholestyramine (used to treat high cholesterol)
- orlistat (anti-obesity agent)
- laxatives, e.g. paraffin oil
- actinomycin (chemotherapy)
- imidazole (antifungal)
- rifampicin (antibiotic)
- isoniazid (antibiotic)
- magnesium-containing products (e.g. antacids)
- phosphorus-containing products in large doses

<PRODUCT NAME> 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.
This high strength formulation is not recommended for use in pregnant and breast-feeding women.

Driving and using machines
<PRODUCT NAME> 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 medicine.

3. How to take <PRODUCT NAME>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will evaluate your dietary habits carefully and take into consideration artificially added vitamin D content of certain food types.
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
The recommended dose is one capsule (25,000 IU) per week for the first month. After the first month, lower doses can be considered.
This initial treatment may be followed by maintenance therapy as determined by your doctor. Your doctor will adjust the dose for you.

Use in children and adolescents

<PRODUCT NAME> 25,000 IU capsules are not intended for use in children and adolescents under 18 years of age. Other forms of this medicine maybe more suitable for children; ask your doctor or pharmacist.

If you take more <PRODUCT NAME> 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 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 <PRODUCT NAME>
Do not take a double dose to make up for a forgotten dose.

If you stop taking <PRODUCT NAME>
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 <PRODUCT NAME> and seek immediate medical help if you experience symptoms of serious allergic reactions (the frequency cannot be estimated from the available data), such as:

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

Uncommon (may affect up to 1 in 100 people):
- hypercalcaemia (high blood calcium levels). You may feel or be sick, loose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion
- 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 the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <PRODUCT NAME>

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 <PRODUCT NAME> 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), caprylic/capric triglycerides, ethanol, glyceride (from sunflower seed oil), oleic acid, ascorbyl palmitate and tocopherol.

What <PRODUCT NAME> looks like and contents of the pack

<PRODUCT NAME> 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, 4, 6, 12 and 50 soft capsules; unit-dose blister packs of 3x1, 4x1, 6x1, 12x1 and 50x1 soft capsules; and hospital packs of 12 and 50 soft capsules.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Teva B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Fabrikant
TEVA Gyógyszergyár Zrt.
Pallagi út 13
Debrecen 4042
Hongarije

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

In het register ingeschreven onder
RVG 128280

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland:	Colecalciferol-ratiopharm 25.000 I. E. Weichkapseln
Italië:	Colecalciferolo Teva B.V.
Nederland:	Vitamine D3 Teva 25.000 IE, zachte capsules
Spanje:	Colecalciferol Teva 25.000 UI capsulas duras

Deze bijsluiter is voor het laatst goedgekeurd in juni 2024.