Package leaflet: Information for the user

Cholecalciferol Teva 20.000 IE, zachte capsules

cholecalciferol

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

<Product name> contains vitamin D_3 which 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_3 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).
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have calcium deposits in your kidneys (nephrocalcinosis).
- if you have kidney stones or serious kidney problems.
- if you 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).
- if you are being treated for heart disease.
- if you are severely restricted in mobility, as there is a risk of increased calcium levels in the blood (hypercalcaemia) or increased calcium levels in the urine (hypercalciuria) in this case.
- when using other medicines containing vitamin D.
- if you have kidney problems or have had kidney stones.

- if you suffer from pseudohypoparathyroidism (rare genetic disorder in which the body's metabolism does not respond to parathyroid hormone (PTH)).

Children and adolescents
This medicine is not recommended 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:
- Cholestyramine (used to treat high cholesterol).
- Phenytoin or barbiturates (used to treat epilepsy).
- Laxatives which contain paraffin oil
- Thiazide diuretics (to treat high blood pressure).
- Glucocorticoids (to treat inflammation).
- Cardiac glycoside (to treat heart conditions), e.g. digoxin.
- Actinomycin (chemotherapy)
- Imidazole (antifungal)
- Orlistat (weight loss aid)
- 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.

During pregnancy and breast-feeding this high dosed product is not recommended and a lower dosed product should be used.

Vitamin D_3 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 D_3 on fertility. However, normal levels of vitamin D are not expected to have any adverse effects on fertility.

Driving and using machines
<Product name> has no known effects on 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 <Product name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Please talk to your doctor, before you take additional calcium.

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

Use in children and adolescents

<Product name> 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.

Use in adults
The recommended dose is: 1 capsule every week for up to 4 – 5 weeks.

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 in the urine (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>
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.

Not known (cannot be estimated from the available data)
Stop taking <Product name> 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, hives, rash (Pruritus/urticaria).

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 that month.

Do not store above 25°C. Store in the original package, in order to protect from light and moisture. Keep blisters in the outer carton.

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 D_3). Each soft capsule contains 0.500 mg cholecalciferol corresponding to 20 000 IU vitamin D_3.

The other ingredients are:
- Capsule fill: medium-chain triglycerides, all-rac-α-Tocopherol (E307).
- Capsule shell: gelatin, glycerol (E422), purified water, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172). Also contains traces of 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 α-tocopherol.

What <Product name> looks like and contents of the pack

<Product name> 20 000 IU capsules are orange, opaque, oval-shaped, soft capsule filled with clear, slightly yellow, oily liquid.

<Product name> is available in PVC/PVdC/aluminium unit dose blisters of 1, 4x1, 10x1, 30x1 and 50x1 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 Pharmaceutical Works Private Limited Company
Pallagi út 13
4042 Debrecen
Hongarije

Merckle GmbH
Graf-Arco-Str. 3
89079 Ulm
Baden-Wuerttemberg
Duitsland

In het register ingeschreven onder: RVG 130081

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

Bulgarije	Prima D3 20 000 IU soft capsules
Duitsland	Colecalciferol-ratiopharm 20 000 I.E. Weichkapseln
Nederland	Cholecalciferol Teva 20.000 IE, zachte capsules
Estland	Senebra
Letland	Senebra 20 000 SV mīkstās kapsulas

Deze bijsluiter is voor het laatst goedgekeurd in september 2023.