

PACKAGE LEAFLET

Package leaflet: Information for the patient

Cholecalciferol Viatris 10.000 IE, zachte capsules Cholecalciferol Viatris 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 Cholecalciferol Viatris, zachte capsules is and what it is used for
2. What you need to know before you take Cholecalciferol Viatris, zachte capsules
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1. What Cholecalciferol Viatris, zachte capsules is and what it is used for

Cholecalciferol Viatris, zachte capsules contains the active substance Cholecalciferol, better known as Vitamin D3.

Cholecalciferol Viatris, zachte capsules is indicated for:

- Prevention and treatment of vitamin D deficiency in adults.
- For prevention of vitamin D deficiency Cholecalciferol Viatris 25.000 IE, zachte capsules is used in adults only in the cases where therapeutic adherence is not obtained with the daily dosing of low dosages of cholecalciferol.

What you need to know before you take Cholecalciferol Viatris, zachte capsules

Do not take Cholecalciferol Viatris, zachte capsules

- If you are allergic to Cholecalciferol (vitamin D3) or any of the other ingredients of this medicine (listed in section 6).
- if you have high levels of calcium in the blood (hypercalcaemia) or in the urine (hypercalciuria)
- if you suffer from kidney stones (nephrolithiasis) or calcium deposits in the kidneys (nephrocalcinosis).
- If you have high levels of vitamin D in the body (hypervitaminosis D).
- If you suffer from a kidney disease (renal failure) (see section “Warnings and precautions”).

Cholecalciferol Viatris, zachte capsules should not be given to infants and children under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cholecalciferol Viatris, zachte capsules, especially:

- if you need to follow a treatment with Cholecalciferol Viatris, zachte capsules for a long period and at high doses.
- If you are elderly person and you are already taking medicines to treat heart diseases (cardiac glycosides or diuretics). In this case, you should check calcium levels in the blood and urine.

- If you are already taking drugs containing vitamin D, food added with vitamin D, or milk enriched with vitamin D.
- If you suffer from a chronic inflammatory disease that may involve all organs called sarcoidosis.
- If you have an impairment of renal function, as vitamin D levels in the body may be altered.
- If you tend to experience kidney stones containing calcium.
- If you have a severe renal insufficiency: in this case other forms of vitamin D should be used.
- If you take this medicinal product for a long term treatment, especially if you are an elderly patient. In this case your doctor will monitor calciuria and renal function. In case of need your doctor will reduce the dose.
- If you have an imbalance of your parathyroid hormone levels (pseudohypoparathyroidism)

Inform your doctor if you have any of the following conditions, as an increase of the dosage as indicated in the section 3. "How to take Cholecalciferol Viatris, zachte capsules" could be needed:

- If you are treated with medicine to treat epilepsy (anticonvulsants or barbiturates).
- If you are treated with medicines for the treatment of inflammation (corticosteroids).
- If you are treated with medicines reducing the level of fats in the blood (colestipol, colestyramine, orlistat and laxatives (such as paraffin oil).
- If you are treated with medicines used for the treatment of the excessive production of acid in the stomach (antiacids containing aluminium).
- If you are obese.
- If you suffer from digestive disorders (intestinal malabsorption, mucoviscidosis, or cystic fibrosis).
- If you suffer from a liver disease (hepatic insufficiency).

Children

Cholecalciferol Viatris, zachte capsules should not be given to infants or children under 18 years of age.

Other medicines and Cholecalciferol Viatris, zachte capsules

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

In particular, tell your doctor if you are taking the following medicines, as they can reduce or increase the effect of Cholecalciferol Viatris, zachte capsules:

- Other medicines containing vitamin D.
- Medicines used for the treatment of epilepsy (anticonvulsants or barbiturates), such as phenytoin, phenobarbital, primidone, etc.
- Medicines to reduce fats in the blood such as colestipol, colestyramine, orlistat and laxatives (such as paraffin oil).
- Antiacids containing aluminium, medicines to treat too much acid in the stomach that can go up to the oesophagus.
- Thiazide diuretics, medicines to treat high blood pressure, increasing the production of urine.
- Digitalis, a medicine to treat some heart disorders.
- Medicines used to treat tuberculosis, as rifampicin or isoniazide.
- Antifungal agents such as imidazole (such as ketoconazole), medicines used to stop the growth of fungal organisms.
- Warfarin, a medicine used to thin blood.
- Medicines for the heart (cardiac glycosides) because you need to be controlled by a doctor, have an ECG if necessary, and control your calcium levels.

Cholecalciferol Viatris, zachte capsules with food and drink and alcohol

Tell your doctor if you take other product containing vitamin D, food added with vitamin D, or in case milk enriched with vitamin D is used, so that he/she can take into account the total dose of vitamin D taken and avoid excessive doses.

The intake of high quantities of alcohol for a long time (chronic alcoholism) decreases vitamin D deposits in the liver.

Pregnancy and breast-feeding

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.

Cholecalciferol Viatris, zachte capsules should not be used during pregnancy and breast-feeding. However, your doctor may decide that your clinical conditions necessarily require a treatment with Cholecalciferol at lower dosages.

Pregnancy

Your doctor will prescribe you vitamin D during the first 6 months of pregnancy only if strictly necessary, due to the risk of harmful foetal effects (see section 3: “If you take more Cholecalciferol Viatris, zachte capsules than you should”).

However, as vitamin D deficiency is harmful to both the foetus and the mother, when required, your doctor will prescribe you vitamin D during pregnancy at lower dosages.

Breast-feeding

When required, your doctor will prescribe you vitamin D at lower dosages during breast-feeding. This does not replace the administration of vitamin D to the infant.

Driving and using machines

Cholecalciferol Viatris, zachte capsules has no or negligible influence on the ability to drive and use machines.

2. How to take Cholecalciferol Viatris, zachte capsules

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

The doses and duration of the treatment shall be assessed by your doctor based on your health conditions.

Do not exceed the doses indicated by your doctor.

Take the dose orally.

Take Cholecalciferol Viatris, zachte capsules with meals.

Cholecalciferol Viatris 10.000 IE, zachte capsules

Adults and Elderly

Prevention:

The recommended dose is 1 capsule every 2 weeks (corresponding to 20,000 IU of vitamin D3 per month).

In case of high risk of deficiency your doctor will evaluate if an increased dosage up to 1 capsule once a week is required (corresponding to 10,000 IU of vitamin D3).

Treatment:

The recommended dose is 2 capsules once a week (corresponding to 20,000 IU of vitamin D3 per week) for 1-3 months. Your doctor will establish the dose that is the most suitable for you and subsequently could prescribe you lower dosages.

In severe vitamin D deficiency in adults and elderly people, the quantity will depend on vitamin D levels and response to treatment. Your doctor will establish the dose that is more suitable for you, based on your response to therapy. Higher doses should be adjusted according to serum levels of hydroxycholecalciferol (25 (OH) D) to be achieved, the severity of the disease and the response to treatment

Long term treatment:

In case of a long-term treatment, especially if you are an elderly patient, your doctor will monitor doses calciuria and renal function. In case of needed your doctor will reduce the dose.

Cholecalciferol Viatris 25.000 IE, zachte capsules

Adults and Elderly

Prevention:

The recommended dose is 1 capsule (corresponding to 25,000 IU of vitamin D3) once a month. In case of high risk of deficiency your doctor will evaluate if an increased dosage up to 2 capsules (corresponding to 50,000 IU of vitamin D3) once a month if required. Your doctor will establish the appropriate dose for you and then could prescribe lower dosages.

Treatment:

The recommended dose is 1 capsule (corresponding to 25,000 IU of vitamin D3) once a week for 4-12 weeks. Your doctor will establish the dose that is the most suitable for you and subsequently could prescribe you lower dosages.

During long-term treatment with high doses calciuria and renal function, especially in elderly patients, must be monitored. It is recommended to reduce the dose or interrupt treatment if the calcium content in the urine exceeds 7.5 mmol / 24 hours (300 mg / 24 hours).

In severe vitamin D deficiency in adults and elderly people, the quantity will depend on vitamin D levels and response to treatment. Your doctor will establish the dose that is the most suitable for you, based on your response to therapy.

Higher doses should be adjusted according to serum levels of hydroxycholecalciferol (25 (OH) D) to be achieved, the severity of the disease and the response to treatment.

If you take more Cholecalciferol Viatris, zachte capsules than you should

In case of accidental ingestion/intake of too much Cholecalciferol Viatris, zachte capsules, tell your doctor immediately or go to the nearest hospital. In case of overdose, increased calcium levels in the blood and urine may occur, whose symptoms are the following: nausea, vomiting, thirst, intense thirst (polydipsia), increased quantity of urine output (polyuria), constipation and dehydration.

Other symptoms of overdose are the following:

Diarrhoea, anorexia, fatigue, headache, muscle and articular pain, muscle weakness, kidney stones, nephrocalcinosis, and renal insufficiency.

Chronic excessive overdoses may lead to deposits of calcium salts in the blood vessels and in organs. The use of too much vitamin D in the first 6 months of pregnancy may cause severe damage to the unborn and newborn child.

If you forget to Cholecalciferol Viatris, zachte capsules

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

If you stop taking Cholecalciferol Viatris, zachte capsules

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

Cholecalciferol Viatris, zachte capsules contains glycerol.

May cause headache, stomach upset and diarrhoea.

May cause allergic reactions.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects reported with the use of vitamin D are the following:

Uncommon side-effects which may affect up to 1 in 100 people:

- Allergic reactions, weakness, loss of appetite (anorexia), increased calcium levels in the blood (hypercalcaemia) and in urines (hypercalciuria).

Rare side-effects which may affect up to 1 in 1,000 people:

Drowsiness, confusion, constipation, breaking wind (flatulence), tummy pain, nausea, vomiting, diarrhoea, metallic taste, dry mouth, skin rash, itching, nettles.

Not Known (the frequency cannot be estimated from the available data):

Headache, Too much calcium in the kidneys (nephrocalcinosis), increased quantity of urine output (polyuria), intense thirst (polydipsia), kidney disease (renal failure).

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 Cholecalciferol Viatris, zachte capsules

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 after EXP. The expiry date refers to the last day of that month.

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.

Store below 25°C.

Store in the original package in order to protect from light.

Do not freeze.

6. Contents of the pack and other information

Cholecalciferol Viatris, zachte capsules contains

Cholecalciferol Viatris 10.000 IE, zachte capsules

- The active substance is cholecalciferol (vitamin D₃). Each soft capsule contains: cholecalciferol (vitamin D₃) 0.250 mg corresponding to 10,000 IU.
- The other ingredients are:
- Fill: olive oil refined, butylhydroxytoluene (E321) Shell: glycerol (E422), titanium dioxide (E171), gelatine and allura Red (E129).

Cholecalciferol Viatris 25.000 IE, zachte capsules

- The active substance is cholecalciferol (vitamin D₃). Each soft capsule contains: cholecalciferol (vitamin D₃) 0.625 mg corresponding to 25,000 IU.
- The other ingredients are:
- Fill: olive oil refined, butylhydroxytoluene (E321) Shell: glycerol (E422), titanium dioxide (E171), gelatine and allura Red (E129).

What Cholecalciferol Viatris, zachte capsules looks like and contents of the pack

Cholecalciferol Viatris 10.000 IE, zachte capsules

The pack contains 2, 4, 8, 10 capsules in a PVC/PVDC and Aluminium thermo-sealed blister.

Cholecalciferol Viatris 25.000 IE, zachte capsules

The pack contains 1, 2, 4 capsules in a PVC/PVDC and Aluminium thermo-sealed blister inserted in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Viatris Limited
Damastown Industrial Park, Mulhuddart
D15XD71, Dublin 15
Ierland

Manufacturer

DOPPEL FARMACEUTICI S.r.l.
Via Martiri delle Foibe, 1
29016 Cortemaggiore (PC)
Italië

In het register ingeschreven onder:

RVG 132323 Cholecalciferol Viatris 10.000 IE, zachte capsules

RVG 132324 Cholecalciferol Viatris 25.000 IE, zachte capsules

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

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

Deze bijsluiter is voor het laatst goedgekeurd in januari 2024.