

NL/H/5338/001-003/IA/001/G

PACKAGE LEAFLET

Package leaflet: Information for the user

Cholecalciferol Pharmemma 50.000 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

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2. What you need to know before you take Cholecalciferol Pharmemma Capsules
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1. What Cholecalciferol Pharmemma Capsules are and what they are used for

The active substance of Cholecalciferol Pharmemma Capsules is vitamin D3. Vitamin D helps the body to absorb calcium and enhances bone formation.

This medicine is recommended in the following cases:

- To prevent vitamin D deficiency in adults.
- To treat vitamin D deficiency in adults.
Vitamin D deficiency may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D.
- For certain bone conditions, such as conditions that affect bone development (osteomalacia), thinning of the bone (osteoporosis), when it will be given to you with other medicines.

Cholecalciferol Pharmemma Capsules are used in adults and the elderly.

2. What you need to know before you take Cholecalciferol Pharmemma Capsules

Do not take Cholecalciferol Pharmemma Capsules:

- if you are allergic to cholecalciferol (vitamin D) or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you have severe kidney problems (severe renal impairment)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have kidney calcium stones or calcium deposits in your kidneys (calcium nephrolithiasis, nephrocalcinosis).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cholecalciferol Pharmemma Capsules if:

- you are on long treatment with this medicine. Your doctor will 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 (glycosides or diuretics), and in case of excess phosphate in your blood (hyperphosphataemia), as well as for patients with increased risk for stones (lithiasis)
- you have kidney damage or disease. Your doctor will need to measure the levels of calcium in your blood or urine
- you have parathyroid hormone imbalance (pseudohypoparathyroidism)
- you have an immune system disorder which may affect your liver, lungs, skin or lymph nodes (sarcoidosis). Your doctor will need to measure the levels of calcium in your blood or urine
- you are already taking additional doses of vitamin D.

Children and adolescents

Do not give this medicine to children and adolescents from the ages of 0 and 17 years.

Other medicines and Cholecalciferol Pharmemma Capsules

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

This is especially important if you are taking:

- diuretics (water tablets). As your doctor will need to monitor your blood calcium levels regularly
- corticosteroids ('steroids' e.g. prednisolone, dexamethasone). As your dose of vitamin D may need to be increased
- colestyramine (a cholesterol lowering medicine) or laxatives (e.g. paraffin oil) or Orlistat. As they reduce vitamin D absorption
- heart medicines (digitalis and other cardiac glycosides). As you should be monitored by a physician and possibly an ECG and your calcium levels monitored
- anticonvulsants (for the treatment of epilepsy e.g. phenytoin), cytotoxic agents actinomycin and imidazole antifungal agents, sleeping medicines (e.g. hydantoin barbiturates) or primidone. As these reduce the effect of vitamin D
- calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin. As these decrease blood calcium levels
- calcium containing products in high doses. As these increase the risk of high blood calcium levels (hypercalcaemia)
- magnesium containing products (e.g. antacids). As these should not be used during long term high dose treatment with vitamin D because of the risk of high magnesium levels
- phosphorus containing products in large doses. As these in large doses increase the risk of high phosphate blood levels.

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.

This high strength formulation is not recommended for use in pregnant and breastfeeding women.

Driving and using machines

Cholecalciferol Pharmemma Capsules has no known effects on ability to drive or use machines.

Cholecalciferol Pharmemma Capsules contain:

Sorbitol: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Cholecalciferol Pharmemma 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.

Adults and Elderly

Dosage

The amount of Cholecalciferol Pharmemma Capsules will depend on your vitamin D levels and on the response given to the treatment.

Prevention of vitamin D deficiency (maintenance):

- for adults and elderly: 800-1600 IU/day or equivalent weekly or monthly dose (1 capsule per month).
- for adults and elderly with osteoporosis: 800-1000 IU/day with a maximum of 2000 IU/day or equivalent weekly or monthly dose (1 capsule per month) in fragile elderly with osteoporosis who are at particular risk of falls and fractures.

Treatment of severe vitamin D deficiency for the adults and elderly (loading dose):

- 800-4000 IU/day or equivalent weekly or monthly dose (1-2 capsules per month).

Alternatively, your doctor may advise you to follow national posology recommendations in treatment of vitamin D deficiency.

Patients with kidney problems

Your doctor may arrange regular blood and/or urine tests for you.

Use in children

Cholecalciferol Pharmemma Capsules is not suitable for children under 18 years.

Method of administration

You should swallow the capsules whole with water, do not chew the capsules.

If you take more Cholecalciferol Pharmemma Capsules than you should

You may develop the following symptoms: loss of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, tiredness, confusion, having to pass urine more than usual, bone pain, kidney problems and in severe cases, irregular heartbeat, coma or even death.

If you take too many capsules, contact your doctor immediately or go to the emergency department of the nearest hospital. Take the packet and any remaining capsules with you.

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

If you forget to take Cholecalciferol Pharmemma Capsules

If you forgot to take a dose of Cholecalciferol Pharmemma Capsules, take the forgotten dose as soon as possible. Then take the next dose at the correct time. However, if it is almost time to take the next dose, do not take the dose you have missed; just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

After that, take the next capsule in accordance with the instructions given to you by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Cholecalciferol Pharmemma Capsules

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 Cholecalciferol Pharmemma Capsules and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing.

Frequency cannot be estimated from the available data.

Side effects with Cholecalciferol Pharmemma Capsules may include:

Uncommon (may affect up to 1 in 100 people):

- too much calcium in your blood (hypercalcaemia). Symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, a need to pass more water than usual, muscle weakness, drowsiness and confusion
- too much calcium in your urine (hypercalciuria).

Rare (may affect up to 1 in 1,000 people):

itching (pruritus), hives (urticaria), rash

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 het Nederlands Bijwerkingen Centrum Lareb, website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cholecalciferol Pharmemma Capsules

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label 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.

6. Contents of the pack and other information

What Cholecalciferol Pharmemma Capsules contains

- The active substance is cholecalciferol:

Each 50,000 IU capsule contains 1250 micrograms Cholecalciferol (vitamin D3), equivalent to 50,000 IU.

- The other ingredients are:

Capsule: medium chain triglycerides and vitamin E acetate (α -tocopheryl acetate) (E307).

Capsule shell: Gelatin (E441), glycerol (E422), sorbitol liquid partially dehydrated, quinoline yellow (E104) and purified water.

What Cholecalciferol Pharmemma Capsules looks like and contents of the pack

- Vitamin D3 50,000 IU Capsules are yellow coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill with dimensions 7.36 mm x 6.27 mm.

Cholecalciferol Pharmemma 50,000 IU Capsules are available in white opaque PVC/PVdC-Al blisters containing 1, 2 or 4 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pharmemma Limited, Unit 2 Ashbourne Manufacturing Park, Ashbourne, Co. Meath, Ireland

Manufacturer:

Copea Pharma Europe Limited, Unit 2, Medici House, Ashbourne Manufacturing Park, Ashbourne, Co. Meath, A84 KH58, Ireland

HC Clover Productos Y Servicios, S.L., C/ Alicante 8-10, Arganda del Rey, Madrid, 28500, Spanje

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