

## **Package leaflet: Information for the patient**

Cholecalciferol Heumann 20.000 IE, zachte capsules

cholecalciferol (Vitamin D<sub>3</sub>)

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

### **1. What Cholecalciferol Heumann is and what it is used for**

The active ingredient in this medicine is cholecalciferol. This is also known as vitamin D<sub>3</sub>. Vitamin D helps your body to absorb calcium. And it helps your body to form new bones better.

This medicine is recommended for initial treatment of clinically relevant vitamin D deficiency in adults.

### **2. What you need to know before you take Cholecalciferol Heumann**

#### **Do not take Cholecalciferol Heumann:**

- 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 vitamin D in your blood (hypervitaminosis D)
- if you have kidney stones (nephrolithiasis) or high levels of calcium in your kidneys (nephrocalcinosis)
- if you have high blood levels of calcium (hypercalcemia) or high urine levels of calcium (hypercalciuria)
- if you have severe problems with your kidneys (severe renal impairment)

#### **Warning and precautions**

Talk to your doctor or pharmacist before taking Cholecalciferol Heumann:

- if you are treated with this medicine for a long time. Your doctor will need to measure the levels of calcium in your blood and urine and check how well your kidneys are working.
- if you have kidney damage or disease. Your doctor will need to measure the levels of calcium and phosphate in your blood or urine.
- if you are being treated for heart disease. For example, with medicines that make the heart pump with more force (cardiac glycosides) such as digoxin.
- if you have sarcoidosis. This is a disease of your body's defenses (the immune system) which may affect your liver, lungs, skin or lymph nodes.
- if your parathyroid glands produce too many hormones and the levels of calcium in your blood is too low (pseudohypoparathyroidism).
- if you are already taking additional doses of vitamin D. If you have symptoms because you have too much vitamin D in your body, the treatment should be stopped.

## **Children and adolescents**

Cholecalciferol Heumann is not indicated for use in children and adolescents.

## **Other medicines and Cholecalciferol Heumann**

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:

- medicines for the heart, for example digitalis. Or other medicines that make the heart pump with more force (cardiac glycosides), for example digoxin. Your doctor may need to check your heart with a heart monitor (ECG) and measure the levels of calcium in your blood.
- medicines to treat epilepsy, such as medicines that make you sleep, sedate, calm you down (barbiturates) or other medicines to treat epilepsy (e.g. phenytoin). These medicines can actually make vitamin D less effective.
- medicines that help reduce inflammation and allergic reactions (corticosteroids), such as hydrocortisone or prednisolone. These medicines can actually make vitamin D less effective.
- medicines that allow you to defecate more easily (laxatives), for example paraffin oil. Or a medicine that makes your cholesterol lower (cholestyramine). Or a medicine to treat very overweight (orlistat). These medicines can cause your body to absorb vitamin D less well.
- a medicine to treat some types of cancer (actinomycin) and medicines containing the substance imidazole that work against fungal infections, such as clotrimazole and ketoconazole. In fact, These medicines can actually make vitamin D less effective.
- diuretic medicines (thiazidediuretics).
- products containing magnesium, for example, antacids. Do not use these drugs if you are being treated with vitamin D for a long time. You will have a risk of having too much magnesium in your blood.
- high amount of products containing phosphorus. For example, calcium channel blockers, heart rate blockers, vitamins and painkillers.
- high amounts of products containing calcium. Concomitant use with calcium-containing products administered in large doses may increase the risk of hypercalcemia. Calcium containing products should not be taken without medical supervision.
- drugs that kill bacteria (antibiotics) such as rifampicin and isoniazid.

## **Cholecalciferol Heumann with food and drink**

You can take Cholecalciferol Heumann with or without food and drink.

## **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, 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 breastfeeding this high dosed product is not recommended and a lower dosed product should be used.*

During pregnancy and breastfeeding adequate vitamin D intake is necessary. The recommended daily intake level for vitamin D during pregnancy and lactation following national guidelines is only around 600 IU.

### Pregnancy

Overdose of vitamin D must be avoided during pregnancy, as prolonged hypercalcaemia can lead to physical and mental retardation, supravalvular aortic stenosis (a heart defect that develops before birth), and retinopathy (a disease of the retina of the eye) of the child.

During pregnancy the daily intake should not exceed 4000 IU vitamin D. Studies in animals have shown reproductive toxicity of high doses of vitamin D.

### Breastfeeding

High-dose vitamin D should not be used during breastfeeding. Vitamin D and its metabolites pass into breast milk. If treatment with Cholecalciferol Heumann is clinically indicated during breastfeeding, this should be considered when giving additional vitamin D to the child.

### Fertility

A normal amount of vitamin D is unlikely to affect your fertility or on your chances of becoming pregnant. Little is known about how large amounts of this medicine affect fertility.

### **Driving and using machines**

This medicine has no or very little effect on your ability to drive or use machines.

### **Cholecalciferol Heumann contains sorbitol**

This medicine contains 14.4 mg sorbitol per soft capsule.

## **3. How to take Cholecalciferol Heumann**

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 dose is determined per person. It depends on how much extra vitamin D you need.

### **Adults**

Recommended dose: One capsule (20 000 IU) per week for up to 4-5 weeks.

After first month, a lower maintenance dose may be considered according to the desirable serum levels of 25-hydroxycholecalciferol (25(OH)D), the severity of the disease and your response to treatment. Alternatively, national posology recommendations in treatment of vitamin D deficiency can be followed. The duration of use is usually limited to the first month of treatment, depending on your doctor's decision.

### **Patients who have problems with their kidneys**

Your doctor may need to monitor your blood and/or urine regularly.

### **Use in children and adolescents**

Cholecalciferol Heumann is not suitable for children and adolescents.

### **Method of administration**

Swallow the capsules whole with some water. Do not chew the capsules.

### **If you take more Cholecalciferol Heumann than you should**

You may experience the following symptoms: weak muscles, pain in your muscles and joints, arrhythmia (irregular heartbeat), inflammation of your pancreas, feeling tired, headache, nausea, vomiting, diarrhoea or constipation, urinating more than usual, calcium in your urine, dry mouth, frequent urination at night (nycturia), protein in your urine, feeling very thirsty, wanting to eat less, feeling dizzy or confused. If you have taken more than you should, contact your doctor or pharmacist immediately.

### **If you forget to take Cholecalciferol Heumann**

If you forget to take your capsule, take the forgotten dose as soon as possible. Then, take the next capsule in accordance with the instructions given to you by your doctor. 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.

### **If you stop taking Cholecalciferol Heumann**

Always consult your doctor or pharmacist before stopping taking this medicine. If you stop taking this medicine too soon, you may start experiencing symptoms associated with too little vitamin D again. 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.

If you experience symptoms associated with a severe allergic reaction, stop taking this medicine and contact a doctor immediately. For example, if you have symptoms such as:

- swollen face, lips, tongue or throat
- difficulty to swallow
- you have a rash on your skin with pink bumps, severe itching (hives) and you cannot breathe properly

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

- too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feeling very thirsty, have muscle weakness, drowsiness or confusion
- too much calcium in your urine (hypercalciuria)

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

- skin rash
- itching
- rash on the skin with pink bumps and severe itching (hives)

**Not known** (cannot be estimated from the available data):

- constipation
- wind
- feeling sick (nausea)
- stomach pain
- diarrhoea

### **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 Heumann**

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.

Store below 25°C and keep in original packaging to protect from light.

Do not throw away any medicines via wastewater or household water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Content of the pack and other information**

### **What Cholecalciferol Heumann contains**

The active substance is cholecalciferol (vitamin D<sub>3</sub>).

Each soft capsule contains 500 micrograms cholecalciferol (vitamin D<sub>3</sub>, equivalent to 20 000 IU).

The other ingredients are:

- **capsule content:** triglycerides, medium-chain, butylated hydroxyanisole (E 320), butylated hydroxytoluene (E 321)
- **capsule shell:** gelatin (E 441), glycerol (E 422), sorbitol liquid, partially dehydrated, erythrosin (E 127), purified water

### **What Cholecalciferol Heumann looks like and content of the pack**

Reddish orange transparant oval shaped soft gelatin capsule containing clear colorless liquid with dimensions  $9.5 \pm 1$  mm long x  $5.5 \pm 1$  mm wide.

Cholecalciferol Heumann is available in blister packs containing 1, 6 or 50 capsules.

Not all pack sizes may be marketed.

### **Houder van de vergunning voor het in de handel brengen**

Heumann Pharma GmbH & Co. Generica KG  
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### **Fabrikant**

Qualimetrix S.A.  
579 Mesogeion Avenue  
Agia Paraskevi  
15343 Athene  
Griekenland

### **In het register ingeschreven onder:**

RVG 132575 Cholecalciferol Heumann 20.000 IE, zachte capsules

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

Nederland: Cholecalciferol Heumann 20.000 IE, zachte capsules  
Duitsland: Colecalciferol Heumann 20 000 I.E. Weichkapseln

**Deze bijsluiter is voor het laatst goedgekeurd in mei 2025**