

## Package leaflet: Information for the user

### Tridolio 24.000 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 Tridolio is and what it is used for
2. What you need to know before you take Tridolio
3. How to take Tridolio
4. Possible side effects
5. How to store Tridolio
6. Contents of the pack and other information

#### 1. What Tridolio is and what it is used for

Tridolio contains cholecalciferol, which is vitamin D3. Vitamin D helps the body to absorb calcium and enhances bone formation.

This medicine may be used in the following cases:

- Treatment of vitamin D deficiency in adolescents and adults.
- Prevention of vitamin D deficiency in adolescents and adults at high risk of vitamin D deficiency.
- With other medicine to treat thinning of the bone (osteoporosis) in adult patients with vitamin D deficiency or at risk of vitamin D deficiency.

#### 2. What you need to know before you take Tridolio

##### Do not take Tridolio:

- 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 kidney calcium stones or calcium deposits in your kidneys (calcium nephrolithiasis, nephrocalcinosis)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Tridolio if:

- you are on initial or long treatment with this medicine. Your doctor may need to measure the levels of calcium in your blood or urine and may need 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 in the kidney or urinary tract (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**

Do not give this medicine to children below 12 years.

### **Other medicines and Tridolio**

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:

- thiazide type diuretics (water tablets), as they reduce the excretion of calcium into the urine. Your doctor may need to monitor your blood calcium levels regularly.
- corticosteroids (medicines for decreasing inflammation and for the treatment of immune disorders and asthma), as they prevent the absorption of calcium. Your dose of vitamin D may need to be increased.
- ion-exchange resins (e.g. colestyramine, a cholesterol lowering medicine) or laxatives (e.g. paraffin oil) or Orlistat, as they reduce vitamin D absorption.
- digitalis and other heart glycosides (medicines to treat heart diseases), as you should be monitored by a physician.
- medicines for the treatment of epilepsy (e.g. phenytoin and barbiturates), actinomycin (chemotherapy) and imidazole (antifungal), as these reduce the effect of vitamin D.
- magnesium containing products (e.g. antacids). 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 high doses, as these increase the risk of high phosphate levels in your blood.
- medicines to treat thinning of the bones (e.g. alendronate), as these decrease the calcium levels in your blood.

### **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.

Adequate vitamin D intake is required during pregnancy and breast-feeding.

#### Pregnancy

This medicine is not recommended for use in pregnant women.

#### Breast-feeding

Vitamin D passes into breast milk. This medicine should not be used during breastfeeding. If treatment with vitamin D is necessary during breastfeeding, your doctor may need to adjust the dose if your child is receiving additional vitamin D.

### **Driving and using machines**

Tridolio has no or negligible effects on the ability to drive or use machines.

### **Tridolio contains Sodium**

This medicine contains less than 1 mmol (23 mg) of sodium per soft capsule that is to say essentially "sodium-free".

## **3. How to take Tridolio**

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 adolescents**

Your dietary habits should be carefully evaluated and artificially added vitamin D content of certain food types should be taken into consideration.

#### Treatment of vitamin D deficiency in adolescents and adults:

For starting treatment of symptomatic vitamin D deficiency the recommended dose is 24 000 IU (1 capsule) per month up to 24 000 IU (1 capsule) per week.

After the first month of treatment a lower dose may be considered, depending on the desired levels of vitamin D in your blood, the severity of the disorder and your response to the treatment.

#### Prevention of vitamin D deficiency in adolescents and adults at high risk of vitamin D deficiency:

The recommended dose is one capsule (24 000 IU) per month.

#### Tridolio taken with other medicines to treat thinning of the bone (osteoporosis) in adult patients with vitamin D deficiency or at risk of vitamin D deficiency:

The recommended dose is one capsule (24 000 IU) per month.

Alternatively, national posology recommendations in treatment of vitamin D deficiency can be followed.

### **Patients with kidney problems**

If you have severe renal impairment the dosage must be determined individually by your doctor, dependent upon desirable levels of vitamin D in your blood, the severity of the disorder and your response to the treatment.

### **Use in children**

Tridolio is not suitable for children below 12 years.

### **Method of administration**

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

### **If you take more Tridolio 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 have taken too many capsules, contact your doctor immediately or go to the emergency department of the nearest hospital. Take the box and any remaining capsules with you.

### **If you forget to take Tridolio**

If you forgot to take a dose of Tridolio, 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 wait for the time of the next dose and continue the administration of the medicine as prescribed by your doctor. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Tridolio**

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

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

Other side effects with Tridolio 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 [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 Tridolio**

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

This medicinal product does not require any special temperature storage conditions.

Keep the blister in the outer carton in order to protect from light.

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 Tridolio contains**

- The active substance is cholecalciferol:  
Each capsule contains 600 micrograms cholecalciferol (vitamin D3), equivalent to 24,000 IU.
- The other ingredients are:

Capsule fill: medium-chain triglycerides, butylhydroxytoluene (E 321)

Capsule shell: carrageenan (E 407), glycerol (E 422), disodium phosphate (E 339), modified starch (E 1440), purified water

### **What Tridolio looks like and contents of the pack**

- Vitamin D3 24 000 IU is a clear, light yellow, oval shaped, soft capsule. It contains a clear, light yellow, oily liquid. Capsule dimensions are 9 mm x 6 mm.

Tridolio 24 000 IU capsules are available in white opaque PVC/PVdC-Al blisters.  
Pack sizes: 4, 6, 8 & 12 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

ZWITTER PHARMACEUTICALS LTD  
34-36 Pentelis Avenue  
15234 Chalandri, Athene  
Griekenland

**Manufacturer**

Catalent Germany Eberbach GmbH  
Gammelsbacher Str. 2  
69412, Eberbach  
Baden-Wuerttemberg  
Duitsland

**In het register ingeschreven onder:**

RVG 131396

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

**Deze bijsluiter is voor het laatst goedgekeurd in maart 2025.**