Package leaflet: Information for the user

Cholecalciferol Wörwag Pharma 800 IE, zachte capsules
Cholecalciferol Wörwag Pharma 5.600 IE, zachte capsules
Cholecalciferol Wörwag Pharma 10.000 IE, zachte capsules
Cholecalciferol Wörwag Pharma 11.200 IE, zachte capsules
Cholecalciferol Wörwag Pharma 20.000 IE, zachte capsules
Cholecalciferol Wörwag Pharma 25.000 IE, zachte capsules
Cholecalciferol Wörwag Pharma 50.000 IE, zachte capsules

cholecalciferol (vitamin D_3)

Read all of this leaflet carefully before you start using 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 <Invented name> is and what it is used for

The active substance is cholecalciferol, also known as vitamin D_3. Vitamin D helps the body to absorb calcium and enhances bone formation.

This medicine is indicated in the following cases:
- For the treatment of vitamin D deficiency in adults and adolescents.
- 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 <Invented name>

Do not take <Invented name>
- 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 calcium deposits in your kidneys (nephrocalcinosis);
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria);
- if you have severe kidney problems (severe renal impairment).

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented name> if:
- you are on initial or long-term treatment with this medicine. Your doctor will need to measure the levels of calcium in your blood or urine and to monitor your kidney function.
- you have kidney damage or kidney disease. Your doctor will need to measure the levels of calcium and phosphate in your blood or urine.
- you are being treated for heart disease, for example with medicines that strengthen the heart's pumping power (cardiac glycosides) such as digoxin.
- you have sarcoidosis. This is a disease of your body's defences (immune system) which may affect your liver, lungs, heart or lymph nodes.
- your parathyroid hormone levels are too high and there is not enough calcium in your blood (pseudohypoparathyroidism).
- you are already taking additional doses of vitamin D.

Children
Do not give this medicine to children below 12 years.

Other medicines and <Invented name>
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:
- Heart medicines, for example digitalis, or other medicines that strengthen the heart's pumping power (cardiac glycosides), e.g. digoxin. Your doctor may check your heart using a heart trace (ECG), and measure levels of calcium in your blood.
- Medicines to treat epilepsy, such as medicines that cause you to fall sleep or anaesthetise you, or that make you calmer (barbiturates). This is because these medicines may reduce the effect of vitamin D.
- Medicines that alleviate inflammation and allergic reactions (corticosteroids) such as hydrocortisone and prednisolone, as these reduce the effect of vitamin D.
- Medicines that make bowel movements easier (laxatives), for example paraffin oil, or a medicine that lowers your cholesterol (cholestyramine), or a medicine used to treat severe overweight (orlistat). These medicines may reduce vitamin D absorption.
- A medicine used to treat some forms of cancer (actinomycin), or medicines containing the substance imidazole, such as clotrimazole and ketoconazole, used to treat fungal diseases. This is because these medicines may reduce the effect of vitamin D.
- Water tablets (thiazide diuretics).
- Magnesium containing products, e.g. antacids. Do not use these medicines if you have been treated with vitamin D for a long time because of the risk of high magnesium levels.
- If you use a lot of products containing phosphorus, e.g. calcium channel blockers, beta blockers, vitamins and pain killers.
- Products that kill bacteria (antibiotics), such as rifampicin and isoniazid.

<Invented name> with food and drink
You can take this medicine with or without food.

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.

Vitamin D passes into breast milk. If you have vitamin D deficiency, you can take the recommended dose of this medicine if you are breast-feeding. This should be considered when giving additional vitamin D to the child.

During pregnancy, the maximum recommended dose is 4 000 IU/day vitamin D. You are advised not to take more than the maximum dose of this medicine during your pregnancy.

Normal level of vitamin D is not expected to have unwanted effects on the fertility or childbearing potential. There is no much known information on impact of high doses on the fertility.

Driving and using machines
This medicine has no or negligible effect on the ability to drive and use machines.

<Invented name> contains sorbitol
This medicine contains 14.4 mg sorbitol in each capsule.

3. How to take <Invented name>

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 individually. It depends on the amount of extra vitamin D you need.

Treatment of vitamin D deficiency in adults and adolescents
800 to 4 000 IU/day, or an equivalent amount per week or per month. The maximum cumulative dose is 120 000 IU for one month.

Prevention of vitamin D deficiency in adults and adolescents
800 to 1 600 IU/day, or an equivalent amount per week or per month. The 50 000 IU dose strength is not suitable for prevention of vitamin D deficiency.

For certain bone conditions such as thinning of the bone (osteoporosis), when it will be given to you with other medicines
800 to 1 000 IU/day, or an equivalent amount per week or per month. The 10 000 IU, 20 000 IU and 50 000 IU dose strengths are not suitable for the osteoporosis indication.

Patients with kidney problems
Your doctor may arrange regular blood and/or urine tests for you.

Use in children
This medicine is not intended for use in children under 12 years of age. Other medicines containing vitamin D may be better for children. Ask your doctor or pharmacist about this.

Method of administration
Swallow the capsules whole with water. Do not chew the capsules.

If you take more <Invented name> than you should
The following symptoms may be experienced: muscle weakness, muscles and joint pain, fatigue, headache, nausea, vomiting, diarrhoea or constipation, excess urine, urinary calcium, dry mouth, urinating often at night (nocturia), urinary protein, intense thirst, loss of appetite, feeling dizzy. If you have taken too much <Invented name>, immediately contact your doctor or pharmacist.

If you forget to take <Invented name>
If you forget to take <Invented name>, take the capsules as soon as you remember. Then take the next dose at the time your doctor told you. However, if it is almost time to take the next dose, do not take the dose you have missed. Take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking <Invented name>
Always talk to your doctor or pharmacist before stop taking this medicine. If you stop taking this medicine too early, you may develop symptoms of vitamin D deficiency 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.

Stop taking this medicine and contact a doctor immediately if you develop symptoms of serious allergic reactions, such as:
- your face, lips, tongue or throat getting bigger than normal
- difficulty swallowing
- a skin rash with pink blisters and severe itching (hives) and not being able to breathe properly.

Other side effects with this medicine may include:

Uncommon (may affect up to 1 in 100 people):
- too much calcium in your blood (hypercalcaemia). You may feel sick or vomit. Or you may: feel like eating less than normal, have constipation, stomach ache, feel very thirsty, have muscle weakness or 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 blisters and severe itching (hives)

Not known (frequency cannot be estimated from the available data):
- constipation
- severe flatulence
- nausea
- abdominal 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 <Invented 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 pack after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C and store in the original package 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 <Invented name> contains

The active substance is cholecalciferol (vitamin D_3).

<Invented name> 800 IU soft capsules
Each soft capsule contains 800 IU cholecalciferol (equivalent to 20 micrograms vitamin D_3).

<Invented name> 5 600 IU soft capsules

Each soft capsule contains 5 600 IU cholecalciferol (equivalent to 140 micrograms vitamin D_3).

<Invented name> 10 000 IU soft capsules
Each soft capsule contains 10 000 IU cholecalciferol (equivalent to 250 micrograms vitamin D_3).

<Invented name> 11 200 IU soft capsules
Each soft capsule contains 11 200 IU cholecalciferol (equivalent to 280 micrograms vitamin D_3).

<Invented name> 20 000 IU soft capsules
Each soft capsule contains 20 000 IU cholecalciferol (equivalent to 500 micrograms vitamin D_3).

<Invented name> 25 000 IU soft capsules
Each soft capsule contains 25 000 IU cholecalciferol (equivalent to 625 micrograms vitamin D_3).

<Invented name> 50 000 IU soft capsules
Each soft capsule contains 50 000 IU cholecalciferol (equivalent to 1 250 micrograms vitamin D_3).

The other ingredients are:
- Capsule contents: medium-chain triglycerides, butylhydroxyanisole (E320), butylhydroxytoluene (E321)
- Capsule shell:
  - *<Invented name> 800 IU soft capsules*
    Gelatine (E441), glycerol (E422), liquid and partially dehydrated sorbitol, FD&C Brilliant Blue FCF (E133), purified water
  - *<Invented name> 5 600 IU soft capsules*
    Gelatine 180 bloom (E441), glycerol (E422), liquid and partially dehydrated sorbitol, FD&C Brilliant Blue FCF (E133), purified water
  - *<Invented name> 10 000 IU soft capsules*
    Gelatine (E441), glycerol (E422), liquid and partially dehydrated sorbitol, FD&C No. 3, Erythrosine (E129), purified water
  - *<Invented name> 11 200 IU soft capsules*
    Gelatine 180 bloom (E441), glycerol (E422), liquid and partially dehydrated sorbitol, FD& C Brilliant Blue FCF (E133), FD&C No. 3, Erythrosine (E129), purified water
  - *<Invented name> 20 000 IU soft capsules*
    Gelatine (E441), glycerol (E422), liquid and partially dehydrated sorbitol, FD&C No. 3, Erythrosine (E129), purified water
  - *<Invented name> 25 000 IU soft capsules*
    Gelatine (E441), glycerol (E422), liquid and partially dehydrated sorbitol, FD&C Brilliant Blue FCF (E133), FD&C No. 3, Erythrosine (E129), purified water
  - *<Invented name> 50 000 IU soft capsules*
    Gelatine (E441), glycerol (E422), liquid and partially dehydrated sorbitol, FD&C Brilliant Blue FCF (E133), purified water

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

<Invented name> 800 IU soft capsules
Soft capsule
Light green, transparent color, oval shape, soft gelatine capsule containing clear, colourless liquid with dimensions 9.5 ± 1 mm long × 5.5 ± 1 mm width.

<Invented name> 5 600 IU soft capsules
Soft capsule
Light blue, transparent color, oval shape, soft gelatine capsule containing clear, colourless liquid with dimensions 9.5 ± 1 mm long × 5.5 ± 1 mm width.

<Invented name> 10 000 IU soft capsules
Soft capsule
Dark orange, transparent color, oval shape, soft gelatine capsule containing clear, colourless liquid with

dimensions 9.5 ± 1 mm long × 5.5 ± 1 mm width.

<Invented name> 11 200 IU soft capsules
Soft capsule
Purple, transparent color, round shape, soft gelatine capsule containing clear, colourless liquid with diameter 6.5 ± 5 mm.

<Invented name> 20 000 IU soft capsules
Soft capsule
Reddish orange, transparent color, oval shape, soft gelatine capsule containing clear, colourless liquid with dimensions 9.5 ± 1 mm long × 5.5 ± 1 mm width.

<Invented name> 25 000 IU soft capsules
Soft capsule
Purple, transparent color, oval shape, soft gelatine capsule containing clear, colourless liquid with dimensions 9.5 ± 1 mm long × 5.5 ± 1 mm width.

<Invented name> 50 000 IU soft capsules
Soft capsule
Dark blue, transparent color, oval shape, soft gelatine capsule containing clear, colourless liquid with dimensions 9.5 ± 1 mm long × 5.5 ± 1 mm width.

The soft capsules are packed in white opaque PVC/PVDC/Aluminium blisters containing:

<Invented name> 800 IU soft capsules: 28, 30, 50, 90 and 250 soft capsules.
<Invented name> 5 600 IU soft capsules: 4, 8 and 12 soft capsules.
<Invented name> 10 000 IU soft capsules: 10 soft capsules
<Invented name> 11 200 IU soft capsules: 2, 4 and 6 soft capsules.
<Invented name> 20 000 IU soft capsules: 1, 6 and 50 soft capsules.
<Invented name> 25 000 IU soft capsules: 4 soft capsules
<Invented name> 50 000 IU soft capsules: 2 soft capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Vergunninghouder:
Wörwag Pharma GmbH & Co. KG
Flugfeld-Allee 24
71034 Böblingen
Duitsland

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

In het register ingeschreven onder:
RVG 132756 Cholecalciferol Wörwag Pharma 800 IE, zachte capsules
RVG 132757 Cholecalciferol Wörwag Pharma 5.600 IE, zachte capsules
RVG 132758 Cholecalciferol Wörwag Pharma 10.000 IE, zachte capsules
RVG 132759 Cholecalciferol Wörwag Pharma 11.200 IE, zachte capsules
RVG 132760 Cholecalciferol Wörwag Pharma 20.000 IE, zachte capsules
RVG 132761 Cholecalciferol Wörwag Pharma 25.000 IE, zachte capsules
RVG 132762 Cholecalciferol Wörwag Pharma 50.000 IE, zachte capsules

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

<To be completed nationally>

Deze bijsluiter is voor het laatst goedgekeurd in juli 2025.