Package leaflet: Information for the patient

Cholecalciferol Acure 20.000 IE zachte capsules
Cholecalciferol Acure 25.000 IE zachte capsules
cholecalciferol (vitamin D_3)

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 <Proposed name> is and what it is used for

<Proposed name> contains cholecalciferol (vitamin D). Vitamin D helps the body to absorb calcium and enhances bone formation.

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

<Proposed name> is indicated in adults.

2. What you need to know before you take

Do not take <Proposed name>
- if you are allergic to cholecalciferol 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 calcium kidney stones (calcium nephrolithiasis) or calcium deposits in your kidneys (nephrocalcinosis)

Warnings and precautions

Do not take more <Proposed name> than your doctor has prescribed, since overdosage may occur. Do not at the same time take other vitamin D containing products (e.g., medicinal products, multivitamin products, dietary supplements containing Vitamin D) other than your doctor has prescribed. This also applies to analogues and metabolites of vitamin D.

Talk to your doctor or pharmacist before taking <Proposed name>, especially if:

- You have high tendency to kidney stone formation.
- You have parathyroid hormone imbalance (pseudohypoparathyroidism).

- if you are being treated for heart disease, especially if you are taking cardiac glycosides or diuretics

During treatment, proper calcium levels and adequate calcium intake preferably by nutrition should be ensured. Concomitant use of calcium containing products administered in large doses may increase the risk of hypercalcaemia and therefore should not be taken without medical advice.

If you have any of the following conditions, your doctor will monitor the levels of calcium or phosphate in your blood, or the level of calcium in your urine:
- if you have kidney problems
- if you suffer from 'sarcoidosis'; an immune system disorder which may affect your liver, lungs, skin or lymph nodes
- if you are immobilized

Other medicines and <Proposed 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:
- medicines for epilepsy such as barbiturates or other anti-convulsants (e.g., carbamazepine, phenobarbital, phenytoin, primidone)
- medicines to control the rate of your heartbeat (e.g., digoxin, digitoxin)
- diuretics (water tablets) such as bendroflumethiazide
- medicines to treat tuberculosis e.g., rifampicin, isoniazid
- medicines leading to fat malabsorption e.g., orlistat, cholestyramine, liquid paraffin
- medicines to treat fungal infections i.e. ketoconazole, itraconazole
- actinomycin (a medicine used to treat some forms of cancer) as it may interfere with the metabolism of vitamin D)
- glucocorticosteroids (steroid hormones such as hydrocortisone or prednisolone).
- medicines containing phosphor
- medicines containing magnesium (e.g., antiacids)

<Proposed name> with food and drink
<Proposed name> should be swallowed whole with water, preferably with the main meal of the day.

Children and adolescents
<Proposed name> 20 000 IU and 25 000 IU Capsules should not be used in children and adolescents (<18 years).

Pregnancy and breast-feeding

During pregnancy and breast-feeding this high dosed product is not recommended and a lower dosed product should be used.
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 Vitamin D.

Driving and using machines

Vitamin D has no or negligible influence on the ability to drive and use machines.

3. How to take <Proposed name>

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

Dose should be established on an individual basis depending on the extent of the necessary vitamin D supplementation.

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

Adults
Medical supervision is necessary as dose requirements may vary dependent on patient response.

For the starting treatment of vitamin D deficiency in adults:
1 capsule of 20 000 IU /week for up to 4-5 weeks
1 capsule of 25 000 IU /week for up to 4 weeks

After first month, a lower maintenance dose should be considered, dependent upon desirable vitamin D levels in the blood, the severity of the disease and the patient’s 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 the doctor's decision.

Method of administration
You should swallow the capsules whole with water, do not chew the capsules, preferably with the main meal of the day.

If you take more <Proposed name> than you should
If you have taken too much <Proposed name>, immediately contact your doctor or pharmacist. An excess of vitamin D results in a disruption of the body's calcium cycle. The following symptoms may be experienced: weakness, fatigue, headache, nausea, vomiting, diarrhoea, excess urine, urinary calcium, dry mouth, nocturia, urinary protein, intense thirst, loss of appetite, vertigo.

If you forget to take <Proposed name>
If you forgot to take a dose of <Proposed name>, 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.

If you stop taking <Proposed name>
This should only happen if you experience side effects. 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 <Proposed name> and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:
- swollen face, lips, tongue or throat
- difficulty swallowing
- hives and difficulty breathing

Side effects with <Proposed name> may include:

Uncommon side effects (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, stomachache, feel very thirsty, have muscle weakness, drowsiness or confusion
- too much calcium in your urine (hypercalciuria).

Rare side effects (may affect up to 1 in 1000 people)
- skin rash
- itching
- hives

Not known (cannot be estimated from the available data):
- constipation
- flatulence
- nausea
- abdominal pain
- diarrhoea
- hypersensitivity reactions such as angio-oedema or laryngeal oedema

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 <Proposed name>

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

Do not store above 30°C. Store in the original package to protect from light and moisture.

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.

6. Contents of the pack and other information

What <Proposed name> Capsules contain
The active substance is cholecalciferol (vitamin D_3). Each capsule contains:
- 500 micrograms of cholecalciferol (vitamin D_3 equivalent to 20 000 IU)
- 625 micrograms of cholecalciferol (vitamin D_3 equivalent to25 000 IU)

The other ingredients are:
- Capsule content: Triglycerides, medium chain, all-rac-α-tocopheryl acetate (E307)
- Capsule shell: Gelatin (E441), glycerol (E422), patent blue V (E131) (only applicable 20 000 IU soft capsule), titanium dioxide (E171) (only applicable 25 000 IU soft capsule), Purified Water

What <Proposed name> looks like and contents of the pack
<Proposed name> 20 000 IU Capsules, soft are transparent, blue, round with 7.2 mm of diameter, soft capsules with a seam in the middle, filled with light yellow viscous liquid.

<Proposed name> 25 000 IU Capsules, soft are white to almost white, oval with 12 mm of length and 6.7 mm of thickness, soft capsules with a seam in the middle, filled with light yellow viscous liquid.

ALU/PVC/PVDC blisters in cartons of 6, 20, 50 or 100 soft capsules for the 20 000 IU.
ALU/PVC/PVDC blisters in cartons of 20, 48, 50 or 100 soft capsules for the 25 000 IU.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Acure Pharmaceuticals Limited
Unit D – Stephenstown Industrial Park, Balbriggan
K32 VR92, Co. Dublin
Ierland

Fabrikant:
Zakłady Farmaceutyczne POLPHARMA S.A.
Oddział Medana w Sieradzu
ul. Wladyslawa Lokietka 10
98-200 Sieradz
Polen

In het register ingeschreven onder:
RVG 128780
RVG 128782

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

Duitsland:	axunio Vitamin D3 20 000 I.E. Weichkapseln
	axunio Vitamin D3 25 000 I.E. Weichkapseln
Nederland:	Cholecalciferol Acure 20.000 IE zachte capsules
	Cholecalciferol Acure 25.000 IE zachte capsules

Deze bijsluiter is voor het laatst goedgekeurd in december 2022.