Bijsluiter: informatie voor de gebruiker

Colecalciferol 1A Pharma 25.000 IE, zachte capsules
Colecalciferol 1A Pharma 50.000 IE, zachte capsules

colecalciferol (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.
- 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 {[Nationally completed name]} is and what it is used for

{[Nationally completed name]} contains colecalciferol (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 (serum level < 25 nmol/L (<10 ng/mL)) in adults.

{[Nationally completed name]} is indicated in adults.

2. What you need to know before you take {[Nationally completed name]}

Do not take {[Nationally completed 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 kidney stones or calcium deposits in your kidneys

Warnings and precautions

Do not take more {[Nationally completed name]} than your doctor has prescribed, since overdose may occur. Do not at the same time take other vitamin D containing products other than your doctor has prescribed. This applies to all forms of vitamin D.

During treatment proper calcium levels and adequate calcium intake preferably by nutrition should be ensured. Supplementary calcium should not be taken without medical advice.

Talk to your doctor or pharmacist before taking {[Nationally completed name]} if you:

- You have high tendency to kidney stone formation.
- You have parathyroid hormone imbalance (pseudohypoparathyroidism).
- if you are being treated for heart disease

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 {[Nationally completed 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 heart beat (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 magnesium (e.g. antacids, which neutralize stomach acidity)
- medicines containing phosphor.

{[Nationally completed name]} with food and drink

{[Nationally completed name]} can be taken independently of meals.

Children and adolescents

{[Nationally completed name]} 25,000 IU and 50,000 IU should not be used in children and adolescents (< 18 years).

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.

{[Nationally completed name]} is not recommended during pregnancy.

Vitamin D passes over into breast milk, so mothers should avoid taking high doses while breast-feeding. {[Nationally completed name]} is not recommended during breastfeeding.

Driving and using machines

{[Nationally completed name]} has no or negligible influence on the ability to drive and use machines.
Investigations have not been performed.

3. How to take {[Nationally completed 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.

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.

The initial loading dose of in total 100,000 IU can be achieved by EITHER, 1 capsule of 25,000IU /week for up to 4 weeks OR 1 to 2 capsules of 50,000 IU in one week.

After completion of this loading dose, a lower maintenance dose should be considered, dependent upon desirable serum levels of 25-hydroxycolecalciferol (25(OH)D), the severity of the disease and the patient's response to treatment.

Alternatively, national dose 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.

If you take more {[Nationally completed name]} than you should

If you have taken too much {[Nationally completed 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 {[Nationally completed name]}

If you forgot to take a dose of {[Nationally completed 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 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 {[Nationally completed 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

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, feel 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):
- pruritus
- rash
- urticaria

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 {[Nationally completed 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 after EXP. The expiry date refers to the last day of that month.

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 {[Nationally completed name]} contains

{[Nationally completed name] 25,000 IU soft capsules}

- The active substance is colecalciferol. Each soft capsule contains 0.625 mg colecalciferol (Vitamin D3), equivalent to 25,000 IU.
- The other ingredients are butylhydroxytoluene (BHT) (E-321), medium chain triglyceride oil, gelatin (E-441), glycerol 99.5% (E-422), titanium dioxide (E-171) and water purified.

{[Nationally completed name] 50,000 IU soft capsules}
- The active substance is colecalciferol. Each soft capsule contains 1.25 mg colecalciferol (Vitamin D3), equivalent to 50,000 IU.
- The other ingredients are butylhydroxytoluene (BHT) (E-321), medium chain triglyceride oil, gelatin (E-441), glycerol 99.5% (E-422), titanium dioxide (E-171), iron oxide red (E-172), and water purified.

What {[Nationally completed name]} looks like and contents of the pack

{[Nationally completed name] 25,000 IU soft capsules} soft capsules are white opaque, size 3, oval soft capsules. Capsule length is approximately 11.3 mm and width is approximately 6.9 mm.
{[Nationally completed name] 50,000 IU soft capsules} are red opaque, size 6, oval soft capsules. Capsule length is approximately 13.5 mm and width is approximately 8.4 mm.

Opaque PVC/PVdC-Alu blister

{[Nationally completed name] 25,000 IU soft capsules} is available in packs containing 1, 2, 3, 4, 8, 10, 12, 14, 20 or 50 soft capsules.
{[Nationally completed name] 50,000 IU soft capsules} is available in packs containing 2, 3, 4, 6, 8, 10, 14 or 50 soft capsules.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder
1 A Pharma GmbH
Industriestraße 18
83607 Holzkirchen
Duitsland

Fabrikanten
GAP S.A.
Agissilaou 46
Agios Dmitrios 173 41
Griekenland

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
Sachsen-Anhalt
39179 Barleben
Duitsland

In het register ingeschreven onder

Colecalciferol 1A Pharma 25.000 IE, zachte capsules	RVG 128774
Colecalciferol 1A Pharma 50.000 IE, zachte capsules	RVG 128775

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

Nederland	Colecalciferol 1A Pharma 25.000 IE, zachte capsules
	Colecalciferol 1A Pharma 50.000 IE, zachte capsules
België	Vitamine D Sandoz 25.000 IU zachte capsules
	Vitamine D Sandoz 50.000 IU zachte capsules

Deze bijsluiter is voor het laatst goedgekeurd in november 2024