

Bijsluiter: informatie voor de gebruiker

Colecalciferol 1A Pharma 800 IE, zachte capsules
Colecalciferol 1A Pharma 3200 IE, zachte capsules

colecalfiferol (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
2. What you need to know before you take {[Nationally completed name]}
3. How to take {[Nationally completed name]}
4. Possible side effects
5. How to store {[Nationally completed name]}
6. Contents of the pack and other information

1. What {[Nationally completed name]} is and what it is used for

{[Nationally completed name]} contains colecalfiferol (vitamin D). Vitamin D helps the body to absorb calcium and enhances bone formation.

This medicine is recommended in the following cases:

800 IU soft capsules

- Treatment of vitamin D deficiency (serum level < 25 nmol/L (<10 ng/mL)) in adults and adolescents.
- Prevention of vitamin D deficiency (serum level < 25 nmol/L (<10 ng/mL)) in adults with an identified risk.

3,200 IU soft capsules

Treatment of vitamin D deficiency (serum level < 25 nmol/L (<10 ng/mL)) in adults and adolescents.

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

Do not take {[Nationally completed name]}:

- if you are allergic to colecalciferol 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

Children

{[Nationally completed name]} 800IU and 3200IU should not be used in children under 12 years of age.

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)
- other vitamin D containing medicines including multi-vitamins
- medicines to control the rate of your heart beat (e.g. digoxin, digitoxin)
- diuretics (water tablets) such as bendroflumethiazide
- calcium supplements
- 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.

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.

Pregnancy

You should not take this medicine during pregnancy without a confirmed vitamin D deficiency and your doctor finds it absolutely necessary for you.

Where there is a vitamin D deficiency the recommended dose is dependent on national guidelines, however, the maximum recommended dose during pregnancy is 4,000 IU/day vitamin D₃. For treatment during pregnancy at higher doses, {{[Nationally completed name]}} is not recommended during pregnancy.

Breast-feeding

{{[Nationally completed name]}} can be used during breastfeeding. Vitamin D passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Fertility

There are no data on the effect of {{[Nationally completed name]}} on fertility. However, normal levels of vitamin D are not expected to have any side effects on fertility.

Driving and using machines

{{[Nationally completed name]}} has no known effects on ability to drive or use machines.

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.

Treatment of Vitamin D deficiency:

800 IU-4,000 IU daily, depending upon the severity of the disease and the patient's response to treatment.

Prevention of vitamin D deficiency:

800 IU- 1,000 IU/ day

The dose should be adjusted, depending upon the desirable serum levels of 25-hydroxycolecalciferol (25(OH)D), the severity of the disease and the patient's response to treatment.

After first month, your doctor may decide to lower a dose. This depends on severity of your disease and yours response to treatment.

Use in children and adolescents

{[Nationally completed name]} 800IU and 3,200IU should not be used in children under 12 years of age.

- Treatment of vitamin D deficiency in adolescents (12-18 years):

800IU-4,000IU/day depending on the severity of the disease and the patient's response to treatment. Should only be given under medical supervision. The daily dose should not exceed 4000IU/day.

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]} 800 IU soft capsules }

- The active substance is colecalciferol. Each soft capsule contains 20 micrograms colecalciferol (Vitamin D3), equivalent to 800 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 yellow (E-172) and water purified.

{[Nationally completed name]} 3,200 IU soft capsules

- The active substance is colecalciferol. Each soft capsule contains 80 micrograms colecalciferol (Vitamin D3), equivalent to 3,200 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 yellow (E-172) and water purified.

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

{[Nationally completed name]} 800 IU soft capsules } are light yellow opaque, size 2, oval soft capsules. Capsule length is approximately 9.5 mm and width is approximately 5.9 mm.

{[Nationally completed name]} 3,200 IU soft capsules } are yellow opaque, size 6, oval soft capsules. Capsule length is approximately 13.6 mm and width is approximately 8.4 mm.

Opaque PVC/PVdC-Alu blister

{[Nationally completed name] 800 IU soft capsules} is available in packs containing 28, 30, 80 or 90 soft capsules.

{[Nationally completed name] 3,200 IU soft capsules} is available in packs containing 7, 30 or 90 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

Correspondentie:

Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikanten

GAP S.A.

Agissilaou 46

Agios Dimitrios 173 41

Griekenland

Salutas Pharma GmbH

Otto-von-Guericke-Allee 1

Sachsen-Anhalt

39179 Barleben

Duitsland

In het register ingeschreven onder

Colecalciferol 1A Pharma 800 IE, zachte capsules RVG 128772

Colecalciferol 1A Pharma 3200 IE, zachte capsules RVG 128773

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

Nederland Colecalciferol 1A Pharma 800 IE, zachte capsules

Colecalciferol 1A Pharma 3200 IE, zachte capsules

België Vitamine D Sandoz 800 IU zachte capsules

Vitamine D Sandoz 3200 IU zachte capsules

Deze bijsluiters is voor het laatst goedgekeurd in oktober 2022.