Package Leaflet: Information for the user

Colecalciferol 20,000 IU Soft Capsules

Read all of this leaflet carefully before you start taking this medicine.

- 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. **Do not pass it on to others.** It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Colecalciferol is and what it is taken for
2. Before you take Colecalciferol
3. How to take Colecalciferol
4. Possible side effects
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1. What Colecalciferol is and what it is taken for

Colecalciferol are soft capsules. They contain the active ingredient:

- **Vitamin D_3** (20,000 IU colecalciferol equivalent to 500 micrograms Vitamin D_3)

Vitamin D is found in the diet and is also produced in the skin after exposure to the sun. Often vitamin D is given in combination with calcium. Colecalciferol is recommended for use when you have a normal intake of dietary calcium.

Colecalciferol may be prescribed by your doctor to treat or prevent vitamin D deficiency. Deficiency of vitamin D may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D (for instance when you are pregnant).

Colecalciferol may also be prescribed for certain bone conditions, such as thinning of the bone (osteoporosis) when it will be given to you with other medicines.

2. Before you take Colecalciferol

Do not take Colecalciferol if you

- are **allergic** (hypersensitive) to vitamin D or any of the other ingredients in the capsules (these are listed in section 6, Further information).
- have high levels of vitamin D in your blood **(hypervitaminosis D)**.
- have high blood levels of calcium **(hypercalcaemia)** or high urine levels of calcium **(hypercalciuria)**.
- have **kidney stones or serious kidney problems.**

Check with your doctor before taking Colecalciferol if

- you have **kidney damage** or **disease.** Your doctor may want to measure the levels of calcium in your blood or urine.
- you are being treated for **heart disease.**
- you have **sarcoidosis** (an immune system disorder which may affect your liver, lungs, skin or lymph nodes).
- you are already taking **additional doses** of **calcium** or **vitamin D.** Whilst you are taking Colecalciferol your doctor will monitor your blood levels of calcium to make sure they are not too high.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular the following medicines may interact with Colecalciferol:

- **Heart medicines** (cardiac glycosides such as digoxin). Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood.
- Medicines to treat epilepsy (such as **phenytoin**) or medicines to make you sleep (**barbiturates** such as phenobarbitone) as these medicines can decrease the effect of vitamin D.
- **Glucocorticoids** (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D.
- **Laxatives** (such as paraffin oil) or a cholesterol lowering drug called **colestyramine** may reduce the absorption of vitamin D.
- **Actinomycin** (a medicine used to treat some forms of cancer) and **imidazole antifungals** (medicines such as clotrimazole and ketoconazole used to treat fungal diseases) as they may interfere with the metabolism of vitamin D.

Taking Colecalciferol with food and drink

You can take Colecalciferol with or without food and drink.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant or you are breast-feeding you should talk to your doctor or pharmacist before you take Colecalciferol.

Due to their high strength, Colecalciferol 20,000IU soft capsules are not recommended during pregnancy and breast-feeding.

Driving and using machines

Colecalciferol should not affect your ability to drive or operate machinery.

3. How to take Colecalciferol

Always take Colecalciferol exactly as your doctor has told you.

Dose

Use in children and adolescents

The recommended dose for:

- Prevention of vitamin D deficiency 12-18 years: 20,000 IU (1 capsule) every 6 weeks
- Treatment of vitamin D deficiency 12-18 years: 20,000 IU (1 capsule) every 2 weeks for 6 weeks.

Colecalciferol 20,000IU soft capsules are **not suitable for children under 12 years.**

Use in pregnancy and breast-feeding

Colecalciferol 20,000 IU soft capsules are not recommended.

Use in adults

The recommended dose for:

- Prevention of vitamin D deficiency: 20,000 IU/month (1 capsule), higher doses may be required in certain situations
- Treatment of vitamin D deficiency: 40,000 IU/week (2 capsules) for 7 weeks, followed by maintenance therapy, (equivalent to 1,400-2,000 IU/day, such as 2-3 capsules per month), based on the advice of your doctor.

You should check with your doctor or pharmacist if you are unsure.

The capsule should be **swallowed whole with water**, preferably with the main meal of the day.

If you take more Colecalciferol than you should

If you accidentally take too many capsules, tell your doctor or get other medical advice immediately. If possible, take the capsules, the box and this leaflet with you to show the doctor. If you take too many capsules you may feel or be sick, become constipated or have stomach pains, weak muscles, tiredness, lack of appetite, kidney problems and in severe cases irregular heartbeats.

If you forget to take Colecalciferol

If you forget to take your capsules, take them as soon as you can. **Do not take a double dose to make up for a forgotten dose.** After that, take the next capsule in accordance with the instructions given to you by your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

(continued overleaf)

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4. Possible side effects

Like all medicines, Colecalciferol can cause side effects, although not everybody gets them.

Side effects with Colecalciferol may include:

Uncommon side effects
(affecting less than 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 side effects
(affecting less than 1 in 1000 people)

- skin rash
- itching
- hives

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colecalciferol

Keep out of the sight and reach of children.

Store below 25°C. Store blister foil in the original container in order to protect from light.

Do not use Colecalciferol after the expiry date which is stated on the carton as "EXP". The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Colecalciferol contains

The active ingredient (which makes the medicine work) is colecalciferol. Each capsule contains 20,000 IU colecalciferol (equivalent to 500 micrograms Vitamin D_3).

The other ingredients are:

Capsule content
Maize oil, refined
Butylated hydroxytoluene (BHT) (E321)

Capsule Shell
Gelatin
Glycerol
Quinoline Yellow (E104)
Purified Water

What Colecalciferol looks like and contents of the pack

Colecalciferol 20,000 IU Soft Capsule is a yellow coloured translucent soft gelatin capsule.

It is available in blister packs containing 7, 10, 14, 15, 20, 28 or 30 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

The Manufacturer is:
Aenova Romania S.R.L., No.20 Carol I Street, Cornu, Prahova, 107180, Romania

This leaflet was last revised in March 2025.

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Produkt/Product : **COLECALCIFEROL 20000IU CAP SD GB_PIL**
STADA Mat.-Nr./Mat.-No.: **9306193 DZ_ 2205GB**
STADA Art.-Nr./Art.-No: **176909/176915**
Hersteller/Manufacturer:
Hersteller Art.-Nr./Manufacturer Art.-No.: **11028079**
Format/Size: **168 x 420 mm**
Schriftgröße/Font-size: **10pt - 12pt**
NTIN/GTIN: **N/A**
PZN/EAN: **N/A**
Pharma-Code: **17595**
Flattermarke/Collating mark: **N/A**
1. Farbe/Colour: **Black + 60% tint**
2. Farbe/Colour:
3. Farbe/Colour:
4. Farbe/Colour:
5. Farbe/Colour:
6. Farbe/Colour:
7. Farbe/Colour:
8. Farbe/Colour:
9. Farbe/Colour:
10. Farbe/Colour:
11. Farbe/Colour:
12. Farbe/Colour:
13. Farbe/Colour:
14. Farbe/Colour:
15. Farbe/Colour:
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