

Package leaflet: Information for the user

Colecalciferol Viatris 800 IU tablets

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 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 Colecalciferol Viatris is and what it is used for
2. What you need to know before you take Colecalciferol Viatris
3. How to take Colecalciferol Viatris
4. Possible side effects
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1. What Colecalciferol Viatris is and what it is used for

Colecalciferol Viatris contains vitamin D₃ which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Colecalciferol Viatris is used to prevent and treat vitamin D₃ deficiency in adults and adolescents.

Your doctor may prescribe Colecalciferol Viatris as an adjunct to specific bone loss medication.

2. What you need to know before you take Colecalciferol Viatris

Do not take Colecalciferol Viatris

- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have kidney stones.

If any of the above applies to you, talk to your doctor or pharmacist before taking Colecalciferol Viatris.

Warnings and precautions

Talk to your doctor or pharmacist before taking Colecalciferol Viatris

- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- when using other drugs containing vitamin D.
- if you have kidney problems or have had kidney stones.

Other medicines and Colecalciferol Viatris

Tell your doctor if you are taking, have recently taken or might take any other medicines.

- Cholestyramine (used to treat high cholesterol).

- Phenytoin or barbiturates (used to treat epilepsy).
- Laxatives which contain paraffin oil.
- Thiazide diuretics (to treat high blood pressure).
- Glucocorticoids (to treat inflammation).
- Cardiac glycosides (to treat heart conditions), e.g. digoxin.
- Orlistat (for weight loss, reduces the amount of fat your body absorbs).

Colecalciferol Viatris with food and drink

Colecalciferol Viatris can be taken with food.

Pregnancy and breast-feeding

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.

Colecalciferol Viatris should only be used during pregnancy if vitamin D deficiency has been clinically established.

Colecalciferol Viatris can be used during breast-feeding. Vitamin D₃ passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Driving and using machines

Colecalciferol Viatris has no known effects on ability to drive or use machines.

Colecalciferol Viatris contains sucrose, isomalt and sodium

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Colecalciferol Viatris.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Colecalciferol Viatris

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

The recommended dose is 1 tablet every day.
The daily dose shall not exceed 4000 IU (five tablets).

The tablets can be swallowed whole or crushed.

Use in children

Colecalciferol Viatris is not intended for use in children under 12 years due to lack of study data.

If you take more Colecalciferol Viatris than you should

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

If you forget to take Colecalciferol Viatris

Do not take a double dose to make up for a forgotten dose.

If you stop taking Colecalciferol Viatris

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 Colecalciferol Viatris and seek immediate medicinal help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing

Uncommon (occurs in less than 1 out of 100 patients): Hypercalcaemia (increased levels of serum calcium) and hypercalciuria (increased levels of urine calcium).

Rare (occurs in less than 1 out of 1 000 patients): Pruritus, rash and urticaria.

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 Colecalciferol Viatris

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 the blister or the bottle after EXP. The expiry date refers to the last day of the month.

Do not store above 30 °C. Store the tablets in the original container, in order to protect from light. Keep the container tightly closed in order to protect from moisture.

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 Colecalciferol Viatris contains

- The active substance is colecalciferol 20 microgram corresponding to 800 IU Vitamin D₃.
- The other ingredients are pregelatinized maize starch, isomalt (E 953), magnesium stearate sucrose, sodium ascorbate (see section 2 “Colecalciferol Viatris contains sucrose, isomalt and sodium”), medium chain triglycerides, silica colloidal anhydrous, modified food (maize) starch and all-rac-alpha-tocopherol.

What Colecalciferol Viatris looks like and contents of the pack

Colecalciferol Viatris is a white to light yellow, biconvex, tablet, 7 mm in diameter.

30, 60 or 90 tablets in blisters.

250 tablets in plastic bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Rottapharm Ltd
Damastown Industrial Park
Mulhuddart
Dublin 15
Ireland

Vemedia Manufacturing B.V.
NL-1112 AX Diemen
Netherlands

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