

Package leaflet: Information for the user

Cacit® D3 500 mg / 440 IU, effervescent granules for oral solution in sachets

Calcium carbonate/colecalciferol

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Cacit D3 is and what it is used for

Cacit D3 contains the active substances calcium carbonate and colecalciferol (Vitamin D₃).

This medicine is used in the elderly for the treatment of deficiency of calcium and vitamin D. It is also used in combination with osteoporosis treatments in patients with, or at high risk of, vitamin D and calcium combined deficiencies.

2. What you need to know before you take Cacit D3

Do not take Cacit D3:

- if you are allergic to the active substances or to any of the other ingredients of this medicine (listed in section 6),
- if you have a disease and/or condition which has resulted in a high concentration of calcium in your urine (hypercalciuria) or blood (hypercalcaemia),
- if you have kidney stones,
- if you have excessive vitamin D levels in your blood (hypervitaminosis D).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Cacit D3.

- if you have impaired kidney function or have a tendency to form kidney stones. Your treatment will need to be monitored carefully if your kidneys are not working properly to ensure you do not build up too much calcium in your blood.
- if you have sarcoidosis (an inflammatory disease of unidentified origin characterised by formation of lumps in different locations).
- if you are an immobilised patient with osteoporosis.

If you are on long-term treatment your doctor may, from time to time wish to check the level of calcium in your blood and take urine sample to monitor kidney function. Depending upon the results, your doctor may reduce the dosage or decide to discontinue the treatment.

Children and adolescents

Cacit D3 is not intended for the use in children.

Other medicines and Cacit D3

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

Consult your doctor if you take any of the following medicines:

- heart medicines such as digoxin or other cardiac glycosides,
- bisphosphonates or sodium fluoride (medicines used to treat bone disorders),
- thiazide diuretics (water tablets),
- phenytoin or barbiturates (medicines used in to treat epilepsy)
- glucocorticosteroids,
- tetracycline antibiotics,
- other medicines containing vitamin D or calcium.

Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken at least two hours before or after Cacit D3.

Cacit D3 with food drink and alcohol

This medicinal product can interact with certain food containing oxalic acid (e.g. spinach and rhubarb), phosphates (e.g. bran) or phytic acid (e.g. whole cereals), since these may reduce the absorption of calcium contained in Cacit D3.

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.

During pregnancy, the daily intake should not exceed 1500 mg calcium and 600 IU vitamin D. In pregnant women, overdoses of calcium and vitamin D should be avoided as permanent hypercalcaemia is related to adverse effects on the developing foetus.

Cacit D3 can be used during breast-feeding, but your doctor should be informed as calcium and vitamin D gets into the breast milk. This should be considered when giving additional vitamin D to the child.

Driving and using machines

Cacit D3 is not expected to affect your ability to drive or operate machinery.

Cacit D3 contains potassium, sodium, sorbitol and sucrose

- This medicine contains 2.1 mmol potassium (81.6 mg) in each sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
- This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.
- Cacit D3 contains 0.6 mg of sorbitol per sachet.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

3. How to take Cacit D3

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults

Pour the contents of the sachet into a glass, add a large quantity of water, stir, then drink immediately the fizzing has stopped. The recommended dosage is one or two sachets per day. Your doctor or pharmacist will tell you how many sachets you need to take a day.

If you take more Cacit D3 than you should

When taking an excessive dose of this medication, the following symptoms may appear: nausea, vomiting, intense thirst, need to pass urine more often, constipation. If any of these effects occur, tell your doctor immediately and take the necessary measures.

In case of prolonged overdose, calcifications may occur in vessels or tissues.

If you forget to take Cacit D3

Do not take a double dose to make up for the missed dose.

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

4. Possible side effects

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

You may suffer an allergic reaction. If you experience rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue, stop taking the medicine immediately and seek urgent medical help.

Uncommon (may affect up to 1 in 100 people):

- high concentration of calcium in the blood (hypercalcaemia). Symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, needing to pass urine more often, muscle weakness, drowsiness and confusion
- increased calcium content of the urine (hypercalciuria)

Rare (may affect up to 1 in 1,000 people):

- constipation, flatulence, nausea, abdominal pain, diarrhoea
- itching, rash and urticaria (hives)

Not known (frequency cannot be estimated from the available data)

- milk alkali syndrome which is associated with high concentration of calcium in the blood (hypercalcaemia), blood pH elevation (alkalosis) and renal insufficiency.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 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 Cacit D3

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

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

Do not store above 25° C.

Do not throw 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 Cacit D3 contains

The active substances in one sachet of 4 g are:

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|-------------------------------|---------------------|
| Calcium carbonate | 1250 mg |
| equivalent to calcium element | 500 mg or 12.5 mmol |

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| Colecalciferol concentrate (powder form) | 440 IU |
| equivalent to colecalciferol (Vitamin D ₃) | 11 µg |

The other ingredients are citric acid, malic acid, gluconolactone, maltodextrin, sodium cyclamate, saccharin sodium, lemon flavour (containing: sorbitol), rice starch, potassium carbonate, sodium ascorbate, modified starch, all-rac-alpha-tocopherol, sucrose, triglycerides medium chain and colloidal anhydrous silica.

What Cacit D3 looks like and content of the pack

4 g sachets (paper/aluminium/polyethylene); boxes of 20, 28, 30, 46, 50, 56, 60 or 100 sachets, sample pack of 10 sachets and multipacks containing 90 (3 packs of 30) sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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