

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

NATECAL D3

600 mg + 400 I.U. chewable tablet

calcium + cholecalciferol



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 is for use in Adults only
- Do not pass this medicine 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 it is in this leaflet:

1. What Natecal D3 is and what it is used for.
2. What you need to know before you take Natecal D3.
3. How to take Natecal D3.
4. Possible side effects.
5. How to store Natecal D3.
6. Contents of the pack and other information.

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

Natecal D3 chewable tablets contain two active substances, calcium carbonate and cholecalciferol (vitamin D₃). Both calcium and vitamin D₃ are found in the diet and vitamin D is also produced in the skin after exposure to the sun. Natecal D3 chewable tablets are used to treat and prevent vitamin D/calcium deficiency.

Natecal D₃ is used:

- In the correction of calcium and vitamin D deficiencies in the elderly,
- In combination with osteoporosis treatments where calcium and vitamin D levels are too low or where there is a high risk of them being too low.

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

Before taking this medicine you should first consult with your doctor or pharmacist to check if your vitamin D or calcium levels are too low or at risk of being too low.

Do not take Natecal D3

- If you are hypersensitive to calcium, vitamin D₃ or to any of the other ingredients of Natecal D3 (in particular soya bean oil)
- If you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- If you are suffering from kidney failure
- If you have kidney stones
- If you have high levels of vitamin D in your blood (hypervitaminosis D)

Warnings and precautions

Talk to your doctor or pharmacist before taking Natecal D3.

- If you have had kidney stones or other kidney problems (your doctor will need to monitor your treatment carefully if your kidneys are not working properly to make sure you do not build up too much calcium in your blood).
- If you stay in bed for a long period (months) and if you have osteoporosis (brittle bones) because you may have high levels of calcium in your blood.
- If you are taking any other medicines containing calcium or vitamin D (your doctor or your pharmacist will be able to tell you if you do).
- If you have sarcoidosis (your doctor will be able to tell you if you do).
- If you are taking these tablets for a long period of time, your doctor may monitor your calcium levels and kidney function via routine testing.

Other medicines and Natecal D3.

Tell your doctor or pharmacist if you are taking:

- Any other medicine containing vitamin D
- The following heart medicines: digoxin or other cardiac glycosides
- Tetracycline and fluoroquinolone antibiotics: it is recommended that you wait at least 3 hours after taking these medicines before taking Natecal D3 chewable tablets.
- Thiazide diuretics
- If you take other drugs used to treat bone disorders, such as bisphosphonates or sodium fluoride, it is recommended that a period of at least 3 hours has to pass before taking Natecal D3 chewable tablets.
- Phenytoin (a medicine for epilepsy) and barbiturates (medicines which are used for epilepsy or which help you sleep), as they may make the vitamin D₃ less effective.
- Rifampicin, makes the vitamin D₃ less effective.
- Orlistat (a medicine used to treat obesity), cholestyramine, laxatives such as paraffin oil, as they may reduce the amount of vitamin D₃ you absorb.
- Estramustin (a medicine used in chemotherapy), thyroid hormones or medicines containing iron, zinc or strontium, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after Natecal D₃.

Natecal D3 with food and drinks

This medicinal product is likely to interact with some foods, for example those containing oxalic acid (like spinach, rhubarb, sorrel, cocoa, tea...), phosphate (e.g. ham, sausages, cheese spread...) or phytic acid (e.g. pulses, whole cereals, chocolate...). Therefore it is recommended to take Natecal D3 two hours before or after meals containing this kind of food.



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Pregnancy and breast-feeding

Natecal D3 chewable tablets should only be used in pregnancy and breast-feeding when it has been recommended by a doctor or pharmacist.

Excipients

This medicinal product contains: sorbitol (E420), aspartame (E951), lactose, hydrogenated soya oil, sucrose, saccharin sodium (E954), sodium croscarmellose (E468).

This medicinal product contains sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor or pharmacist before you take or receive this medicine.

This medicinal product contains 5 mg aspartame in each chewable tablet, which is equivalent to 0.007 mg/kg. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicinal product contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking this medicine. Sucrose may be harmful to the teeth.

This medicinal product contains hydrogenated soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

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

3. How to take Natecal D3

Always take Natecal D3 exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and elderly is one tablet twice a day (e.g. one in the morning and one in the evening) preferably after meals.

The tablets may be chewed or sucked, they must not be swallowed whole.

If you take more Natecal D3 than you should

Contact your doctor. If you cannot do this, go to your nearest hospital accident and emergency (casualty) department, taking any remaining tablets and the packaging with you.

If you forget to take Natecal D3

Take it as soon as you remember. Then take your next dose at the usual time. However, if it is almost time for your next dose, skip the missed dose and continue as usual. Never take two doses at the same time.

4. Possible side effects

Like all medicines, Natecal D3 can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking Natecal D3 and contact your doctor IMMEDIATELY or go to your nearest Hospital:

- Serious allergic (hypersensitivity) reactions such as swelling of the face, lips or tongue. The frequency of these effects is not known (cannot be estimated from the available data).

The following effects are uncommon: (may affect up to 1 in 100 people)

- hypercalcaemia (too much calcium in your blood) - the 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
- hypercalciuria (too much calcium in your urine)

The following effects are rare: (may affect up to 1 in 1,000 people)

- nausea
- stomach ache
- constipation
- diarrhoea
- flatulence
- itching
- rash
- hives

Other special population

Patients with kidney failure could have a potential risk of high levels of phosphate in the blood, kidney stones and too much calcium being deposited in the kidneys.

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 YellowCard Scheme Website: 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 Natecal D3

- Keep out of the sight and reach of children.
- Store in the original package in order to protect from moisture.
- Do not take Natecal D3 after the expiry date which is stated on the box after "exp". The expiry date refers to the last day of that month.
- 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 to protect the environment.
- After first opening, the shelf life is 60 days.

6. Contents of the pack and other information

What Natecal D3 contains

- Each tablet contains the active substances: calcium carbonate (1500 mg equivalent to 600 mg calcium) and cholecalciferol (vitamin D₃) (400 I.U. equivalent to 0.01 mg).
- The other ingredients are: sorbitol (E 420), maltodextrin, croscarmellose sodium (E 468), aspartame (E 951), saccharin sodium (E 954), lactose monohydrate, aniseed flavour, peppermint flavour, molasses flavour, magnesium stearate, all-rac- α -Tocopherol (E 307), hydrogenated soya bean oil, gelatine, sucrose, maize starch, silicon dioxide.

What Natecal D3 looks like and contents of pack

This medicinal product is a chewable tablet.

The tablet has a round, bevelled edge shape and is white to almost white with the inscription "D" on one side.

Tablet container containing 12 or 60 tablets.

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Phone 0161 488 5555 for help