



NATECAL D3 orodispersible tablets

600 mg of calcium (carbonate) + 400 U.I. of cholecalciferol (Vit. D3)

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.
- This medicine is for use in Adults only.
- 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.

In this leaflet:

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

Natecal D3 orodispersible 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 orodispersible tablets may be prescribed by doctors 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. Before you take Natecal D3

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).

Take special care with 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 or other products 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);

Taking other medicines

Do not take the product without talking to 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 orodispersible tablets.
- Thiazide diuretics;
- If you take other drugs used to treat bone disorders, such as biphosphonates or sodium fluoride, it is recommended that a period of at least 3 hours has to pass before taking Natecal D3 orodispersible 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.
- 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.

Taking Natecal D3 with food and drinks - This 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.

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

Important information about some of the ingredients of Natecal D3 - The product contains: aspartame (E951), lactose, hydrogenated soya bean oil, sucrose.

The product contains aspartame, which is a source of phenylalanine. Phenylalanine may be harmful for people with phenylketonuria; The product contains lactose and sucrose therefore if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine; The product contains soya oil, therefore if you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Natecal D3

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

The usual 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 put in the mouth without any water and sucked, they must not be swallowed whole.

You will feel the tablets to dissolve in your mouth in a few minutes; this will be accompanied by a mild effervescence.

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.

The following effects are uncommon: (occur in between 1 and 10 out of every 1,000 patients)

- 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: (occur in between 1 and 10 out of every 10,000 patients)

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

The frequency of the following effects is not known (cannot be estimated from the available data):

- Serious allergic (hypersensitivity) reactions such as swelling of the face, lips or tongue.

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.

5. How to store Natecal D3

- Keep out of the reach and sight of children.
- Do not store above 25° C.
- 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 and on the tablet container after “exp”. The expiry date refers to the last day of that month.
- After first opening, the shelf life is 60 days.
- 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 Natecal D3 contains

The active substance are:

- Each orodispersible tablet contains: 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: maltodextrin, aspartame (E 951), hydroxypropyl cellulose low-substituted (E 463), lactose monohydrate, citric acid anhydrous (E 330), orange flavour, stearic acid, DL- α -tocopherol (E 307), hydrogenated soya bean oil, gelatine, sucrose, maize starch.

What Natecal D3 looks like and contents of pack - This medicinal product is an orodispersible tablet. The tablet has a round, bevelled edge shape and is white to almost white. Container containing 60 tablets.

Marketing Authorisation Holder and Manufacturer

ITALFARMACO S.p.A. – Viale F. Testi, 330 – 20126 Milano (Italy).