

# NATEMILLE

## CALCIUM / VITAMIN D<sub>3</sub>

600 mg / 1000 I.U.

**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 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, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

### What is in this leaflet:

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

#### 1. What NATEMILLE is and what it is used for

NATEMILLE is used to prevent and treat calcium or vitamin D3 deficiency in the elderly, and as an additional treatment in the management of osteoporosis, when a risk of deficiency of calcium and vitamin D3 is suspected.

NATEMILLE contains calcium and vitamin D3 which both are important components for the formation of bone. Vitamin D3 regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Ask your doctor, pharmacist or other health personal if you have further questions and always follow their instructions. You must talk to a doctor if you do not feel better or if you feel worse after some days.

#### 2. Before you take NATEMILLE

##### Do not take NATEMILLE

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

##### Warnings and precautions

Talk to your doctor or pharmacist before taking NATEMILLE

- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- if you are taking other drugs containing vitamin D or calcium.
- if you have poor kidney function or high tendency of renal stone formation.
- if you are immobilized with osteoporosis.

##### Other medicines and NATEMILLE

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

The effect of the treatment can be affected if this drug is taken simultaneously with certain other drugs against:

- high blood pressure (thiazide diuretic)
- heart problems (cardiac glycosides such as digoxin)
- high cholesterol (cholestyramine)
- constipation (laxatives such as liquid paraffin)
- epilepsy (phenytoin or barbiturates)
- inflammatory conditions/suppression of immunity (corticosteroids)
- obesity (orlistat)

Please make sure your doctor knows if you are taking any of the medicines listed above. Your dosage may need to be adjusted.

##### If you simultaneously use a certain drug for;

- osteoporosis (bisphosphonates)

you should take this at least one hour before you take NATEMILLE

##### If you simultaneously use certain drugs for;

- infection (quinolones)

you should take these two hours before or six hours after taking NATEMILLE.

##### If you simultaneously use certain drugs for;

- infection (tetracyclines)

you should take these two hours before or four to six hours after taking NATEMILLE.

##### If you simultaneously take certain drugs for;

- dental caries (sodium fluoride)
- anaemia (iron)

you should take these drugs at least three hours before taking NATEMILLE.

##### If you simultaneously use a certain drug for;

- hypothyroidism (levothyroxine)

you should separate the intake with NATEMILLE by at least four hours.

##### NATEMILLE with food and drink and alcohol

The calcium absorption may be inhibited by food containing oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals). You should wait at least two hours before you take NATEMILLE if you have eaten food with high content of oxalic acid or phytic acid.

##### Pregnancy and breast-feeding and fertility

During pregnancy the daily intake should not exceed 1500 mg calcium and 600 IU vitamin D.

NATEMILLE is therefore not recommended during pregnancy.

NATEMILLE can be used during breast-feeding. Calcium and vitamin D3 pass over into breast milk. This should be considered when giving additional vitamin D to the child.

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.

##### Driving and using machines

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

##### NATEMILLE contains aspartame.

Aspartame is a source of phenylalanine. Phenylalanine may be harmful for people with phenylketonuria;

##### NATEMILLE contains lactose and sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine;

##### NATEMILLE contains soya oil.

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

#### 3. How to take NATEMILLE

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

The dosage is individually decided for you by your doctor.

Usual dose: 1 tablet daily.

The tablets may be sucked, they should not be swallowed whole.

The tablets should be taken preferably after meals

The amount of calcium in NATEMILLE is lower than the usually recommended daily intake. NATEMILLE is therefore meant for patients with need for additional vitamin D, but with a dietary intake of 500-1000 mg of calcium per day. Your dietary intake of calcium should be estimated by your doctor.

NATEMILLE are not intended for use in children and adolescents.

##### If you take more NATEMILLE than you should

If you may have taken more NATEMILLE than you should, talk to your doctor or pharmacist immediately.

Some symptoms of overdose of NATEMILLE are loss of appetite, thirst, abnormal increased urine secretion, nausea, vomiting and constipation.

##### If you forget to take NATEMILLE

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. 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.

You should stop taking NATEMILLE and see your doctor immediately 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/or hypercalciuria (increased levels of urine calcium).

Rare (occurs in less than 1 out of 1 000 patients) constipation, flatulence, nausea, abdominal pain, diarrhoea, pruritus, rash and urticaria.

Not known (cannot be estimated from the available data): serious allergic reactions.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### 5. How to store NATEMILLE

Keep out of the sight and reach of children.

Keep container tightly closed. Do not use NATEMILLE after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. Keep the container tightly closed in order to protect from moisture.

After first opening, the shelf life is 60 days.

Do not use this medicine if you notice any sign of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask a pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What NATEMILLE contains

The active substances are calcium carbonate 1500 mg corresponding to calcium 600 mg and cholecalciferol 25 microgram corresponding to 1000 IU Vitamin D3.

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- $\alpha$ -tocopherol (E 307), partially hydrogenated soya bean oil, gelatine, sucrose, maize starch.

##### What NATEMILLE looks like and contents of the pack

NATEMILLE is an orodispersible tablet, white to almost white, with round, bevelled edge shape, 30 tablets in the bottle.

##### Marketing Authorisation Holder and Manufacturer:

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