

## PACKAGE LEAFLET

### CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet

**Read all of this leaflet carefully before you start using this medicine. It contains important information for your treatment**

If you have any further questions, if you have any doubt, ask your doctor or pharmacist

- . Keep this leaflet, you may need to read it again.
- . If you need further information and advices, please ask your pharmacist.
- . If symptoms worsen or persist, consult your doctor.
- . If you notice any side effects not listed in this leaflet or if any of the side effects gets serious, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. WHAT CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet IS AND WHEN IT IS USED FOR?
2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet?
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4. WHAT ARE THE POSSIBLE SIDE EFFECTS?
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#### **1. WHAT CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet IS AND WHEN IT IS USED FOR?**

Pharmacotherapeutic class: MINERAL SUPPLEMENTS.

ATC code: A12AX

(A: gastrointestinal system and metabolism).

This medicine is indicated:

- in the elderly in the event of calcium and vitamin D deficiency,
- in combination with treatments for osteoporosis when calcium and vitamin D intake is insufficient.

#### **2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet ?**

**Never use CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet in the following cases:**

- history of allergy to vitamin D or one of the ingredients,
- prolonged immobilisation,
- abnormally high calcium level in the blood (hypercalcaemia),
- abnormally high excretion of calcium in the urine (hypercalciuria),
- kidney stone (calcium calculus),
- phenylketonuria (hereditary disease due to an enzyme deficiency) due to the presence of aspartame.

**Take special care with CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet in case of:**

- Prolonged treatment: it is necessary to regularly control the quantity of calcium eliminated in the urine (calciuria). Depending on the result, your doctor may reduce and even discontinue your treatment.
- Supplementary administration of high doses of calcium and vitamin D, which require strict medical monitoring.
- Concomitant treatment with bisphosphonates and treatment with an antibiotic of the cycline series: it is recommended to wait at least 2 hours between intake of those medicines and CALCIFORTE VITAMIN D3, tablet to be chewed, sucked or dispersed.
- Sarcoidosis or kidney failure.
- Fructose intolerance (hereditary metabolic disease), glucose-galactose malabsorption syndrome and sucrase-isomaltase deficiency (rare metabolic diseases) due to the presence of sucrose and sorbitol.

**Taking or using other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, in particular digitalis derivatives, cyclines, bisphosphonates, estramustine, iron salts and thiazide diuretics, including medicines obtained without a prescription.

**Pregnancy and breast feeding**

In the event of pregnancy, do not exceed 1500 mg of calcium and 600 IU of vitamin D3 per day. Ask your doctor or pharmacist for advice before taking any medicine.

Excipients with known effect: aspartame, sorbitol, sucrose, soy proteins.

**3. HOW TO USE CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet ?**

**Posology**

The daily dose is 2 tablets per day or 1 tablet morning and evening, to be chewed, sucked or dissolved in a little water.

If you have the impression that the effect of CALCIFORTE VITAMIN D3 is too strong or too weak, ask your doctor or pharmacist.

**Method of administration**

Oral route.

**If you use more CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet than you should:**

Immediately inform your doctor or pharmacist.

Taking an overdose of this medicine may cause the following symptoms: nausea, vomiting, intense thirst, constipation.

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

**If you forget to take CALCIFORTE VITAMINE D3, chewable, suckable or dispersible tablet:**

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

#### 4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet can cause side effects, although not everybody gets them:

- Constipation or diarrhoea,
- Bloating, stomach pain
- Excessive increase in the calcium concentration of the blood or urine in the event of prolonged treatment
- Risk of allergic reactions (urticaria, generalised allergic reaction) due to the presence of soy proteins

#### Statement of the side effects:

If you feel any adverse effect, tell it to your doctor or your pharmacist or your nurse. This also applies to any adverse effect which would not be mentioned in this leaflet. You can also declare adverse effects directly via the national system of statement: the National Agency for safety of medicines and health products (ANSM) and the Regional Centers of Pharmacovigilance. The web site: [www.ansm.sante.fr](http://www.ansm.sante.fr). By reporting the adverse events, you contribute to supply more information on the medicine safety.

#### 5. HOW TO STORE CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet?

Keep out of the reach and sight of children.

Do not use CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet after the expiry date which is stated on the box.

Store at a temperature not exceeding +25°C.

Medicines should not be disposed of via waste-water or household wastes. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

#### 6. FURTHER INFORMATION

**What does CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet, contain?**

#### **The active substances are:**

Calcium element.....	500.00 mg
Equivalent to calcium carbonate .....	1250.00 mg
Cholecalciferol or vitamin D3.....	400 IU
Equivalent to cholecalciferol concentrate, powder form	
<i>Saccharomyces cerevisiae</i> yeast .....	50.00 mg

For one tablet

#### **The other ingredients are:**

Pregelatinised starch, sorbitol, glycerol dibehenate, sodium croscarmellose, aspartame, orange flavour powder.

Coating of the concentrate of cholecalciferol: alpha-tocopherol, edible fats, gelatin, sucrose, maize starch.

**What is CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet and contents of the outer pack ?**

This medicine contains chewable, suckable or dispersible tablets. Box of 60 tablets or 180 tablets.

**Marketing Authorisation Holder :**

LABORATOIRES GRIMBERG - 19 rue Poliveau - 75005 Paris

**Manufacturer:**

Laboratoires GRIMBERG - ZA des Boutries - rue Vermont - 78704 Conflans Sainte Honorine cedex

This leaflet was last approved on 18 February 2010