

Package leaflet: information for the user

CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet

Calcium carbonate, vitamin D₃, *Saccharomyces cerevisiae* yeast

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. WHAT CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet
3. HOW TO TAKE CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet
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1. WHAT CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: MINERAL SUPPLEMENTS, ATC code: A12AX

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.

You must talk to a doctor if you do not feel better or if you feel worse

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet

Do not take CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet if:

- you are allergic (hypersensitive) to actives substances or any of the other ingredients of this medicine listed in section 6
- you have prolonged immobilisation,
- you have abnormally high calcium level in the blood (hypercalcaemia),
- you have abnormally high excretion of calcium in the urine (hypercalciuria),
- you have kidney stone (calcium calculus),
- you have phenylketonuria (hereditary disease due to an enzyme deficiency) due to the presence of aspartam
- you are allergic to peanuts or soy, due to the presence of soy protein

Warnings and precautions

Talk to your doctor or pharmacist before taking 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 requires strict medical monitoring.
- Concomitant treatment with cyclin, digoxin, bisphosphonates, estramustine, thyroid hormones, strontium, zinc: 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.

Other medicines and CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicine, in particular cyclin, bisphosphonates, estramustine, iron salts, thyroid hormones, strontium, zinc, rifampicin, ciprofloxacin, norfloxacin, integrase inhibitor, enzyme-inducing anticonvulsants, thiazide diuretics and orlistat, 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.

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.

CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet contains the excipients with known effect: aspartam, sorbitol, sucrose, soy proteins.

- This medicine contains 381.0 mg sorbitol in each tablet. 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 described as an inability to break down fructose, talk to your doctor before you take or receive this medicine.
- This medicine contains 10.0 mg aspartam in each tablet. Aspartam is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine increases because the body cannot remove it properly.
- If your doctor has told you that you have an intolerance to some sugars, contact your doctor before you take or receive this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say essentially 'sodium-free'.
- If you are allergic to peanut or soy, do not use this medicinal product (see section 2 "Do not take CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet if:"

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3. HOW TO TAKE CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet

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

Posology

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

If you feel the effect of CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet is too strong or too weak, consult your doctor or pharmacist.

Method of administration

Oral route.

If you take 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, excessive urination.

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

If you forget to take CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet

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

4. POSSIBLE SIDE EFFECTS

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

- Constipation or diarrhoea.
- Bloating, stomach pain.
- Nausea
- Excessive increase in the calcium concentration of the blood or urine in the event of prolonged treatment.
- Pruritus, skin rash, urticaria

- Risk of allergic reactions (urticaria, generalised allergic reaction) due to the presence of soy proteins.

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via your national reporting system.

By reporting side effects, you can help provide more information on the safety of this medicine.

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

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

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

Store at a temperature not exceeding +25°C.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet contains

- The active substances are:

Calcium element.....	500.00 mg
Equivalent to calcium carbonate	1250.00 mg
Cholecalciferol or vitamin D3.....	400.00 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*.

*Composition of the orange flavour powder: maltodextrin, soy proteins, gum arabic, concentrated orange juice, essential oil of orange, essential oil of lemon, citral, acetaldehyde, linalol, ethyl butyrate, alpha-terpineol, octanal, ethyl acetate, geranyl acetate.

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

What CALCIFORTE VITAMIN D3, chewable, suckable or dispersible tablet looks like and contents of the pack?

This medicine contains chewable, suckable or dispersible tablets. Box of 60 tablets or 180 tablets in blister (PVC/PVDC/aluminium).

Marketing Authorisation Holder:

LABORATOIRES GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

Manufacturer:

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