

PACKAGE LEAFLET

CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium

Read all of this leaflet carefully before you start taking this medicine. It contains important information about your treatment.

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

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1. WHAT CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: MINERAL ELEMENT, ATC code: A12AA20

This medicine contains calcium.

It is recommended:

- in the event of calcium deficiency due to an increase in requirements (growth, pregnancy, lactation)
- as ancillary treatment for bone decalcification in the elderly or after the menopause, corticosteroid therapy or prolonged immobilisation after resumption of mobility.

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

2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium?

Do not take CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium if:

- you are allergic (hypersensitive) to active substances or any of the other ingredients of this medicine, listed in the section 6.
- hypercalcaemia (abnormally high concentration of calcium in the blood),
- hypercalciuria (abnormally high excretion of calcium in the urine),
- calcium calculus (kidney stone) - tissue calcification,
- prolonged immobilisation accompanied by hypercalciuria and/or hypercalcaemia: calcium is only to be administered when mobility has been resumed,

Excessive calcium intake may be dangerous. **DO NOT USE THIS MEDICINE WITHOUT A MEDICAL ADVICE.**

Warnings and precautions

Talk to your doctor or pharmacist before taking CALCIFORTE 500 mg, oral solution in ampoule sweetened with sodium cyclamate and saccharin sodium.

Use this medicine *WITH CAUTION* in the event of prolonged treatment or kidney failure: it is necessary to control the urinary and blood calcium concentrations.

OTHER MEDICINES AND CALCIFORTE 500 MG, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium

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

Pregnancy and breast – feeding

This medicine, can be used during pregnancy and breast-feeding under normal conditions of use.

If you are pregnant or you are breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say it is essentially "sodium-free".

3. HOW TO TAKE CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium?

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.

FOR ADULTS AND CHILDREN AGED OVER 6 YEARS.

The recommended dose is:

Adult

2 ampoules daily

Children

Child aged 6 to 10 years old: 1 ampoule a day

Child above 10 years old: 2 ampoules a day

Method and route of administration

Oral route.

Since the presence of yeast induces a deposit, shake the ampoule before opening it, then dilute the contents in a glass of water. Preferably take during a meal.

CALCIFORTE 500 mg self-breaking ampoules are pre-filled. To open an ampoule take a tip between your thumb and forefinger and, with a sharp movement cause the breakage. Present the opened ampoule above a glass before starting again the same operation on the second tip.

Use in children and adolescents

ONLY FOR CHILDREN OVER 6 YEARS OF AGE

If you have taken more CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium than you should have:

Immediately inform your doctor or pharmacist.

If you forget to take CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium for oral suspension

Do not take a double dose to make up for the dose you forgot.

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.

- Gastrointestinal disorders: constipation, flatulence, nausea.

- In the event of prolonged high-dose treatment: risk of a change in the calcium concentration of the blood or urine.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. 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 500 MG, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium?

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

Store at a temperature not exceeding 25°C.

Do not use this medicine after the expiry date which is stated on the outer carton after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicine 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. PACKAGING CONTENTS AND FURTHER INFORMATION

What CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium contains.

• **The active substances are :**

Calcium gluconate	1.050 g
Calcium lactate pentahydrate	1.280 g
Calcium glucoheptonate	0.930 g
Calcium chloride	0.544 g
Yeast <i>Saccharomyces cerevisiae</i>	0.030 g

Per 10 ml ampoule.

• **The other ingredients are:**

Lactic acid, saccharin sodium, ammonium glycyrrhizinate, lemon-mirabelle plum flavour, sodium cyclamate, water

What CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium and contents of the outer pack.

Oral solution in a 10-ml ampoule; box of 30. .

Marketing Authorisation Holder:

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

Manufacturer:

Laboratoires GRIMBERG - ZA des Boutries - Rue Vermont - 78704 Conflans Sainte Honorine Cedex- France

This leaflet was last revised in September 2020.