

PACKAGE LEAFLET

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

Calcium gluconate, Calcium lactate, Calcium glucoheptonate, Calcium chloride, Saccharomyces cerevisiae yeast

Read all of this leaflet carefully before you start taking this medicine. It contains important information about 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 informations or advice, ask your pharmacist.

If your symptoms get worse or persist, consult a 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

Keep out of the reach of children

What does this leaflet contain?:

1. WHAT CALCIFORTE 500 MG, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium IS AND WHAT IT IS USED FOR ?
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?
3. HOW TO USE CALCIFORTE 500 MG, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium?
4. WHAT ARE THE POSSIBLE SIDE EFFECTS?
5. HOW TO STORE CALCIFORTE 500 MG, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium?
6. PACKAGING CONTENTS AND FURTHER INFORMATION

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

CALCIUM / MINERAL ELEMENT

(A: gastrointestinal system and metabolism)

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 (sensitive) to active substances or one of the ingredients contained in this medicine, mentioned in the paragraph 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,

SPECIAL WARNINGS

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

PRECAUTIONS FOR USE

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.

WARNING AND PRECAUTIONS

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

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 using, have recently used or might use any other medicines.

PREGNANCY – BREAST-FEEDING

In the normal conditions of use, this medicine may be prescribed during pregnancy and breast-feeding.

If you are pregnant or you breast-feed, or you think to be pregnant or plan to get pregnant, seek for advice of your doctor or pharmacist before taking this medicine.

3. HOW TO USE 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.

DOSAGE

FOR ADULTS AND CHILDREN AGED OVER 6 YEARS.

The recommended dose is:

In adult: 2 ampoules daily

In child:

Child from 6 to 10 years old: 1 ampoule daily

Child over 10 years old: 2 ampoules daily

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.

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

Consult your doctor or pharmacist immediately.

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 a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. WHAT ARE THE 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.

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.signalement-sante.gouv.fr. By reporting the adverse events, you contribute to supply more information on the drug safety.

5. HOW TO STORE CALCIFORTE 500 MG, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium?

Keep out of the reach and sight of children.

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

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. PACKAGING CONTENTS AND FURTHER INFORMATION :

What does CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium contain?

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 (Saccharomyces cerevisiae).....	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 is CALCIFORTE 500 mg, oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium and contents of the outer pack?

This medicine is an oral solution in a 10-ml ampoule; box of 30.

Holder and operating company:

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

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