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*.**
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.

In this leaflet:

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. 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.

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?

This medicine IS NOT TO BE USED in the following cases:
- history of allergy to one of the ingredients,
- 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,

IF IN DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

SPECIAL WARNINGS

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

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.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

INTERACTIONS WITH OTHER MEDICINE PRODUCTS AND OTHER FORMS OF INTERACTION
IN ORDER TO PREVENT POTENTIAL INTERACTIONS BETWEEN SEVERAL MEDICINES, ALWAYS TELL YOUR DOCTOR OR PHARMACIST OF ANY OTHER ONGOING TREATMENT.

PREGNANCY - LACTATION

In the event of deficiency, your doctor may prescribe this medicine during pregnancy or lactation.
In general, ask your doctor of pharmacist for advice before taking any medicine.

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

DOSAGE
FOR ADULTS AND CHILDREN AGED OVER 6 YEARS.

Adults and children aged over 10 years: 2 ampoules daily
Children aged 6 to 10 years: 1 ampoule daily

THIS MEDICINE HAS BEEN PRESCRIBED FOR YOU PERSONALLY IN A PRECISE SITUATION:
. IT MAY NOT BE SUITABLE FOR ANOTHER CASE
. DO NOT ADVISE ANYONE ELSE TO TAKE IT

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 need further information how to use this medicine, ask your doctor or pharmacist.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?

LIKE ANY ACTIVE PRODUCT, THIS MEDICINE MAY INDUCE MORE OR LESS UNPLESANT EFFECTS IN CERTAIN PEOPLE :
- 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.ansm.sante.fr.By reporting the adverse events, you contribute to supply more information on the medicine 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 CALCIFORTE 500 MG, **oral solution in an ampoule sweetened with sodium cyclamate and saccharin sodium** after the expiry date which is stated on the box.
The expiry date means the last day of the month.
Store at a temperature of less than 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 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?

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

Holder and operating company:

Laboratoires GRIMBERG - 19, rue Poliveau - 75005 Paris - FRANCE

Manufacturer:

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

This leaflet was last approved on 20th September 2012