SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

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

QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium gluconate .....1.0500 g
Calcium lactate pentahydrate .....1.2800 g
Calcium glucoheptonate .....0.9300 g
Calcium chloride .....0.5440 g
Yeast (Saccharomyces cerevisiae) .....0.0300 g

per 10-ml ampoule

One ampoule: 500 mg of elemental calcium.
For a full list of excipients, see the section "List of excipients".

PHARMACEUTICAL FORM: Oral solution in an ampoule.

CLINICAL PARTICULARS

Therapeutic indications

Calcium deficiencies, particularly during growth, pregnancy and lactation.
Ancillary treatment for osteoporosis (senile, post-menopausal, on corticosteroid therapy, associated with immobilisation following resumption of mobility).

Posology and method of administration

FOR ADULTS AND CHILDREN OVER 6 YEARS OLD

Posology

Oral route

In adults:
Calcium deficiency and osteoporosis: 1 g of elemental calcium daily i.e. 2 ampoules daily.
In children:
Calcium deficiency during growth periods:
- children from 6 to 10 years old: 500 mg of elemental calcium daily, i.e. 1 ampoule daily.
- children over 10 years old: 1 g of elemental calcium daily, i.e. 2 ampoules daily.

Method of administration

The presence of yeast induces a deposit. Shake the ampoule before opening it. Dilute the contents in a glass of water. Preferably to be taken during a meal.

Contra-indications

- Hypersensitivity to the actives substances or one of the excipients mentioned in the section "List of excipients"
- Hypercalcaemia, hypercalciuria, calcium calculus, tissue calcification.
- Prolonged immobilisation accompanied by hypercalciuria and/or hypercalcaemia: calcium treatment is only to be administered after resumption of mobility.

Special warnings and precautions for use

Concomitant administration of calcium and vitamin D requires strict monitoring of serum and urinary calcium.

In case of kidney failure, regularly control serum and urinary calcium and avoid administration of high doses.

In the event of long-duration treatment and/or kidney failure, it is necessary to control calciuria and reduce or interrupt temporary treatment if urinary calcium exceeds 7.5 mmol/24 h (300 mg/24 h) in the adult and 0.12 to 0.15 mmol/kg/24 h (5 to 6 mg/kg/24 h) in children.

Interactions with other medicinal products and other forms of interaction
In particular, in case of combination with vitamin D:

Combinations to be taken into account:

+ Thiazide diuretics:
Risk of hypercalcaemia due to decreased urinary elimination of calcium.

Combinations requiring a precaution for use:

+ Cyclines:
Decreased digestive absorption of cyclines.
Take the calcium salts remotely from the cyclines (more than 2 hours if possible).

+ Digitalis:
Risk of arrhythmia.
Clinical monitoring and, if appropriate, control of the ECG and serum calcium.

+ Bisphosphonates:
Risk of decreased digestive absorption of bisphosphonates.
Take the calcium salts remotely from the bisphosphonates (more than 2 hours if possible).

Fertility, pregnancy and breast-feeding:
This medicine may be used during pregnancy and breast-feeding. However, the daily dose should not exceed 1500 mg of calcium

Adverse events
Gastrointestinal disorders as like: constipation, flatulence, nausea.
Hypercalciuria, hypercalcaemia (in case of prolonged high-dose treatment)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Agence nationale de sécurité du medicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.signalement-sante.gouv.fr

Overdose

Symptoms: thirst, polyuria, polydipsia, nausea, vomiting, dehydration, hypertension, vasomotor disorders, constipation.
In children: arrested growth (weight and height) may precede all the above signs.

Treatment: discontinuation of calcium intake and, if appropriate, vitamin D; rehydration and, depending on the seriousness of the intoxication: use alone or in combination of a diuretic, corticosteroid and calcitonin, possibly combined with peritoneal dialysis.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

CALCIUM / MINERAL ELEMENT
(A: gastrointestinal system and metabolism)

Pharmacokinetic properties
Absorption: calcium is mainly absorbed in the proximal small intestine by means of an active transport mechanism that is subject to saturation and dependent on vitamin D.
Calcium absorption in that form is equivalent to about 30% of the dose ingested.

Elimination: calcium is excreted in the sweat and digestive secretions.
Urinary calcium concentration depends on glomerular filtration and the rate of tubule reabsorption of calcium.

Preclinical safety data
No information is available

PHARMACEUTICAL PARTICULARS

List of excipients

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

** Composition of the lemon-mirabelle plum flavour*: lemon alcoholature, mirabelle plum alcoholature, apple alcoholature, raspberry, amyl acetate, ethyl acetate, butanol, propanol, gamma-undecalactone, benzaldehyde, vanillin, asperula tincture, Tonka bean extract.

Shelf life: 3 years

Special precautions for storage:
Store at a temperature less than 25°C.

Nature and contents of the container:
Ampoule with 2 break-open tips, type II amber glass of 10 ml.

Special precautions for disposal and other handling:
Any unused product or waste material should be disposed of in accordance with current regulations.

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

8. MARKETING AUTHORISATION NUMBER(S)
3400933298296 or 332 982-9:10-ml ampoule (yellow glass); box of 30

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 August 1996/12 August 2011

9. DATE OF REVISION OF THE TEXT
10 August 2017

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription