SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. 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.

3. PHARMACEUTICAL FORM: Oral solution in an ampoule.

4. CLINICAL PARTICULARS

4.1.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).

4.2. Posology and method of administration

FOR ADULTS AND CHILDREN AGED OVER 6 YEARS
Oral route.
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.
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 aged 6 to 10 years: 500 mg of elemental calcium daily, i.e. 1 ampoule daily.
- children aged over 10 years: 1 g of elemental calcium daily, i.e. 2 ampoules daily.

4.3. Contra-indications

- Hypersensitivity to one of the ingredients,
- 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.

4.4. Special warnings and precautions for use

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

In the event 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.

4.5. Interactions with other medicinal products and other forms of interaction

In particular, in case of combination with vitamin D:

Combination 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).

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

4.7. Effects on the ability to drive and use machines: Not applicable

4.8. Adverse effects

Gastrointestinal disorders: constipation, flatulence, nausea.

Hypercalciuria, hypercalcaemia (in the event 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.ansm.sante.fr

4.9. 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 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.

5.3. Preclinical safety data: No information given

6. PHARMACEUTICAL PARTICULARS

6.1. 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.

6.2 Incompatibilities:

Not applicable

6.3. Shelf life: 3 years

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

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

6.6. Special precautions for disposal: No special requirements

7. MARKETING AUTHORISATION HOLDER: Laboratoires GRIMBERG - 19, rue Poliveau - 75005 Paris - 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:

12/08/1996

9. DATE OF REVISION OF THE TEXT: 20/09/2012