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	1.050 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

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 breast-feeding.
- 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

Oral route

Posology

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 active 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.

This medicine contains less of 1 mmol sodium (23 mg) by ampoule, that is to say essentially “sodium free”.

Interactions with other medicinal products and other forms of interactions <u>Combinations to take into account:</u>

Thiazide and apparent diuretics:

Risk of hypercalcemia due to decreased urinary excretion of calcium.

<u>Combinations requiring a precaution for use:</u>

+ Digoxin
Risk of serious arrhythmias.
Clinical monitoring and, if necessary, monitoring of ECG and serum calcium.

+ Bisphosphonates
For oral calcium salts: decrease in digestive absorption of bisphosphonates.
Take calcium salts away from bisphosphonates (from at least 30 minutes to more than 2hours, if possible, depending on the bisphosphonate).

+ Estramustine
Decreased digestive absorption of estramustine.
Take calcium salts away from estramustine (more than 2 hours, if possible).

+ Iron
With oral iron salts: decreased digestive absorption of iron salts.
Take iron salts away from a meal and in the absence of calcium.

+ Thyroid hormones
Decreased digestive absorption of thyroid hormones.
Take calcium salts away from thyroid hormones (more than 2 hours, if possible).

+ Cyclines
Decreased digestive absorption of cyclins.
Take calcium salts away from cyclins (more than 2 hours, if possible).

+ Strontium
With oral calcium salts: decreased digestive absorption of strontium.
Take strontium away from calcium salts (more than 2 hours, if possible).

+ Zinc
Decreased digestive absorption of zinc by calcium.
Take calcium salts away from zinc (more than 2 hours, if possible).

Fertility, pregnancy and breast-feeding

Pregnancy

This medicine may be used during pregnancy. However, the daily dose should not exceed 1500 mg of calcium

Breast-feeding

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

Undesirable effects

Gastrointestinal disorders : constipation-like, flatulence-like, nausea-like.
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, arterial 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

Pharmacotherapeutic group: MINERAL SUPPLEMENTS, ATC code: A12AA20

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.

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. Box of 30.

Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with current requirements.

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

MARKETING AUTHORISATION NUMBER(S)

34009 332 982 9 6:10-ml ampoule (yellow glass); box of 30

DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 August 1996/12 August 2011

DATE OF REVISION OF THE TEXT
25 September 2020

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription