SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Centrum CA-C 1000 (ORANGE) EFFERVESCENT TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Pharmaceutical Ingredients	
Ascorbic acid	1.000 mg
Calcium carbonate	0.327 mg
Calcium lactate gluconate	1.000 mg

Calcium carbonate 327 mg, calcium lactate and gluconate 1 g corresponding 260 mg of calcium, and 1 g of ascorbic acid.

Excipients: Saccharin, sucrose, sodium hydrogen carbonate, sucrose, beta-carotene yellow powder.
{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

1 effervescent tablet contains: Calcium carbonate 327 mg, calcium lactate and gluconate 1 g corresponding 260 mg of calcium, and 1 g of ascorbic acid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Increased need for calcium and vitamin C (ascorbic acid), e.g., during periods of rapid growth (childhood, puberty), in the elderly, during pregnancy and lactation, during infectious diseases and during convalescence.
- To prevent a lack of calcium and vitamin C.
- As adjuvant therapy for colds and flu infections.

4.2 Posology and method of administration

Posology

Adults and children above 8 years: the recommended dose is one effervescent tablet daily.

The safety an efficacy of Centrum Ca-C 1000 (Orange) in children below 8years and infants has not been established

Method of administration

Dissolve the effervescent tablet in a glass of water (approx. 200 ml) and drink immediately. Centrum Ca-C 1000 Orange effervescent tablet may be taken with or without food.

4.3 Contraindications

- Hypersensitivity to any of the active substances or excipients according to the composition.
- Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria (e.g., hyperparathyroidism, vitamin D overdose, plasmacytoma, bone metastases).
- Severe renal failure, nephrocalcinosis, nephrolithiasis (oxalocalcic renal lithiasis). Iron storage disorders.

4.4 Special warnings and precautions for use

The medication should not be administered for a prolonged period at higher than recommended doses.
For patients with a history of mild hypercalciuria (calcium excretion >300 mg/24 hours or >7.5 mmol/24 hours), or urinary calculi, monitoring of calcium excretion in the urine is required. If necessary, the calcium dose should be reduced, or therapy should be discontinued.
An increased fluid intake is recommended for patients prone to formation of calculi in the urinary tract.
In patients with impaired renal function, calcium salts should be taken under medical supervision only, with monitoring of calcium and phosphate serum levels.

During high-dose therapy and especially during concomitant treatment with vitamin D, there is a risk of hypercalcaemia occurrence with subsequent kidney function impairment (see "Overdose"). In these patient's serum calcium concentration and renal function should be monitored.
In addition, increased caution with the product should be taken in the case of sarcoidosis, heart failure or in patients receiving digitalis therapy.

There have been literature reports alluding to possible increased absorption of aluminium with citrate salts. Calcium C 1000 effervescent tablets (which contain citric acid) should be used with caution in patients with impaired renal function and especially those receiving aluminium-containing medications (such as certain antacids).

Patients with severely impaired renal function (see "Contraindications") should not exceed a daily intake of 50 to 100 mg of ascorbic acid due to the risk of hyperoxalataemia and accumulation of oxalate crystal deposits in the kidneys.

Calcium and ascorbic acid must be used with caution in patients who excrete oxalate in urine due to the increased risk of calcium oxalate calculi formation.

4.5 Interaction with other medicinal products and other forms of interaction

Calcium may affect the absorption of oral tetracyclines and quinolones, as well as of bisphosphonates, L-thyroxine and fluoride-based products.

Calcium C intake may reduce *quinolone* absorption due to the possible formation of insoluble compounds. In case of concomitant use, an interval of at least 3 hours should be observed between each intake.

The concomitant administration of calcium may also reduce the absorption of *tetracycline*- or *doxycycline-based medications*. Therefore, these medications should be administered at least 2 hours before or 4 to 6 hours after oral intake of Calcium C.

Cardiac glycoside toxicity may increase with hypercalcaemia resulting from treatment with calcium. These patients require monitoring through regular ECGs and serum calcium level checks.

In the case of concomitant use of oral *bisphosphonates* or of *sodium fluoride* with calcium-based preparations, gastrointestinal absorption of oral bisphosphonates and sodium fluoride may be reduced. This is why oral bisphosphonates must be administered at least three hours prior to the calcium intake. Co-administration of vitamin D and its derivatives increases calcium absorption.

Systemic corticosteroids reduce the absorption of calcium. In case of concomitant intake, an increase of the calcium dose may be necessary.

Oxalic acid (found in spinach, rhubarb or cacao) and *phytic acid* (found in whole cereals or bran) may inhibit calcium absorption through formation of insoluble compounds with calcium. Patients should not take any calcium-based preparations within 2 hours after consumption of foods with high oxalic or phytic acid content.

Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

At high doses, in co-administration with vitamin D, calcium may reduce the effect of verapamil and probably that of other calcium antagonists.
Concomitant intake of ascorbic acid and *aluminium-based antacids* may cause increased aluminium absorption. Ascorbic acid should not be taken with aluminium-containing antacids (see "Warnings and precautions").

Ascorbic acid facilitates iron availability for chelation. Given that Calcium C contains a high dose of ascorbic acid (>200 mg), this medication should not be administered concomitantly with deferoxam

4.6 Pregnancy and lactation

Pregnancy

No controlled study has been conducted in pregnant women or animals. Under these conditions, the medication will be administered only with a medical prescription.
If treatment is initiated in the third trimester of pregnancy, the daily dose of calcium should not exceed 1,500 mg.

It is recommended that overdoses of calcium be avoided during pregnancy. Prolonged hypercalcaemia has been linked with deleterious effects on the foetus during growth.

Administration of high doses of vitamin C during pregnancy is not recommended given that the resulting enhanced metabolism may cause symptoms of deficiency in neonates and infants.

Lactation
Breastfeeding Calcium and vitamin C are passed through breast milk.

Fertility
There are no relevant data available.

4.7 Effects on ability to drive and use machines

Centrum Ca-C 1000 (Orange) has no influence on the ability to drive or use machines.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000) or unknown (cannot be estimated from the available data).

Immune system disorders
Rare: hypersensitivity, for example, skin eruption, pruritus, urticaria.
Very rare: isolated cases of systemic allergic reactions (anaphylactic reaction, face oedema, angioedema).
Metabolism and nutrition disorders
Uncommon: hypercalcaemia, hypercalciuria. *Gastrointestinal disorders*
Rare: bloating, constipation, diarrhoea, nausea, vomiting, abdominal pain.
Renal and urinary disorders

Undetermined frequency: urinary lithiasis (in the case of susceptibility to renal calculi, prolonged treatment with high doses of calcium and vitamin C may induce the formation of calculi) (see "Warnings and precautions").

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agency.

4.9 Overdose

Overdose leads to hypercalciuria and hypercalcaemia. Symptoms of hypercalcaemia may include: nausea, vomiting, thirst, polydipsia, polyuria, dehydration and constipation. Chronic overdose with resulting hypercalcaemia can cause vascular and organ calcification.
The calcium intoxication threshold is more than 2,000 mg per day over a period of several months.

High doses of ascorbic acid may cause osmotic diarrhoea accompanied by respective abdominal symptoms.

Ascorbic acid overdose in patients with iron storage disorders (e.g., sideroblastic anaemia, haemochromatosis), see "Contraindications", may lead to iron overload and cause red blood cell haemolysis in patients with a genetic red blood cell glucose-6-phosphate dehydrogenase deficiency.

Treatment of overdose
In case of an intoxication, treatment should be stopped immediately, and the fluid deficiency should be corrected.

The overdose should be treated by hydration, with a sodium chloride solution administered intravenously if needed. A loop diuretic (e.g., furosemide) may then be used to further increase calcium excretion and to prevent volume overload. Thiazide diuretics, however, should be avoided. In patients with renal failure,

hydration is ineffective, and they should undergo dialysis. In the case of persistent hypercalcaemia, contributing factors should be excluded, e.g., vitamin A or D hypervitaminosis, primary hyperparathyroidism, malignant tumour, renal failure, or immobilisation (see "Contraindications" and "Warnings and precautions")

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ATC Code: A11GB01

Calcium is a mineral substance of vital importance that plays a major role in the maintenance of electrolyte equilibrium in the body and for the proper functioning of numerous regulatory mechanisms. Calcium deficiency causes neuromuscular disorders and bone demineralisation.
Ascorbic acid (vitamin C) plays an important role in the processes of oxidation and biological reduction and in cellular respiration. Furthermore, it is essential for collagen formation and for repair processes at the tissue level.

The value of administering high doses of vitamin C as a preventive measure against colds has not yet been clearly proven (positive and negative conclusions of double-blind clinical studies).
Calcium and ascorbic acid deficiency may be the result of an inadequate diet or may be a symptom of various disorders associated with increased need (see "Indications/Possible uses").

Calcium C effervescent tablets provide enough vitamin C and ionisable calcium to meet daily requirements during periods of increased need, in supplementation of a balanced diet.

5.2 Pharmacokinetic properties

Pharmacokinetics
No pharmacokinetic study has been conducted with Calcium C.

Calcium:
Centrum Ca-C 1000 (Orange)contains calcium in the form of soluble and ionisable salts.

Absorption
Generally, 30% of the calcium contained in food is absorbed. The mechanisms of active transport are present only in the upper portion of the small intestine. The quantity absorbed is also dependent on the calcium need.
Absorption is enhanced by vitamin D, lactose and proteins and is inhibited by phytates, sulphates, fatty acids and oxalates.

Distribution
Bones and teeth contain 99% of the body's total calcium. Fifty percent of serum calcium is present in ionised form and 5% in anionic compound form. The remaining 45% is bound to plasma proteins (albumin).

Elimination
Renal elimination is approximately 20%. The remaining 80% is partially excreted as non-resorbable calcium and partially excreted by the bile ducts and pancreas in faeces.
Calcium excretion is reduced in patients with chronic renal failure (see "Warnings and precautions").
Vitamin C
Vitamin C is rapidly absorbed from the gastrointestinal tract and is widely distributed in the tissues. Excess

amounts of vitamin C are excreted in urine.

5.3 Preclinical safety data

No preclinical data specific to this product is available.

Specific remarks

Effect on diagnostic methods

High doses of ascorbic acid (in excess of 1 g per day) may distort blood and urine test results (e.g.,certain glucose testing methods

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients		
Beta-carotene 1% yellow powder	Coloring agent	HSE
Bitter flavour powder	Flavouring agent	HSE
Citric acid anhydrous	Acidifier	Ph. Eur.
Lemon flavour powder	Flavouring agent	HSE
Macrogol 4000	Lubricant agent	Ph. Eur.
Saccharin sodium	Sweetening agent	Ph. Eur.
Sodium hydrogen carbonate	Effervescent agent	Ph. Eur.
Sucrose	Sweetening agent	Ph. Eur.
Magnesium stearate	External lubricant	Ph. Eur

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 MONTHS

6.4 No Special precautions for storage

The medication should not be used after the date following "EXP" on the container stated on the label.

Store below 30°C. Protect from moisture and light. Store in the original package.
Keep the tube tightly closed.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Pack size is 10 effervescent tablets
Polypropylene tube for 10 effervescent tablets without aluminium foil and a tamperproof polyethylene stopper with compensator and desiccant (1.4 g).

The product contact surfaces (Polyethylene and Polypropylene) are commonly used in food and pharmaceutical packaging and comply with the European Commission Directive 2002/72/EC.

6.6 Special precautions for disposal <and other handling>

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

7 MANUFACTURER

Manufactured by
Famar Orleans
5, Avenue de Concyr
Orleans, Cedex 02, 45071
France.

MARKETING AUTORISATION HOLDER

For French Speaking Africa markets (FSA):
Haleon France
23, rue François Jacob
92500 Rueil-Malmaison – France

For East Africa markets (EA):
GlaxoSmithKline Limited
Likoni Road, Industrial Area
P.O. Box 78392-00507
Nairobi - Kenya

8. MARKETING AUTHORISATION NUMBER

2460

9. DATE OF FIRST REGISTRATION

26/07/2026

10. DATE OF REVISION

26/07/2026