SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Effervescent Calcium Gluconate Tablets BP 1g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1g Calcium Gluconate BP equivalent to 2.23mmol of calcium (Ca^{2+})

Excipient with known effect
Each tablet contains 102.8 mg sodium.
For the full list of excipients, see section 6.1

3 Pharmaceutical Form

White uncoated tablets.

White, circular, flat bevelled-edge uncoated tablets impressed “C” and the identifying letters “CN” on one face.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

1) As an adjunct to conventional therapy in the arrest or slowing down of bone demineralisation in osteoporosis where other effective treatment is contraindicated.
2) In the arrest or slowing down of bone demineralisation in osteoporosis where other effective treatment is contraindicated.
3) Therapeutic supplementation in osteomalacia, rickets, post-gastrectomy malabsorption, pregnancy, lactation, malnutrition or dietary deficiency.

4.2. Posology and Method of Administration

Posology
The tablets must be dissolved in one third to one half a tumblerful of water.

In health the concentration of calcium in serum is maintained close to 2.5mmol/l (normal range 2.25-2.75mmol or 4.5-5.5mEq/l).

Treatment or therapeutic supplementation should aim to restore or maintain this level.

Adults (including elderly):
Osteoporosis: A daily supplement of 800mg (20mmol) calcium or 8-9 tablets may reduce the rate of bone loss, but larger doses have not been shown to be more effective.

Indication:	Daily dosage:
Osteoporosis **Post-gastrectomy malabsorption** **Osteomalacia and rickets** **Lactation**	12-20 tablets
Pregnancy supplement **Pregnancy cramps**	1-10 tablets

Children: Children require approximately half the adult dosage.
Infants: A more suitable dosage form should be used for this age group.

Method of Administration
To be dissolved in water for oral administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Severe hypercalcaemia and hypercalciuria (*eg* in hypervitaminosis D, hyperparathyroidism, severe renal failure and renal calculi, osteoporosis due to immobility and decalcifying tumours such as plasmocytoma and skeletal metastases).

4.4 Special warnings and precautions for use

Calcium salts should be given cautiously to patients with cardiac disease or sarcoidosis.
Careful monitoring of blood levels and urinary calcium excretion is necessary, particularly when high dose or parenteral calcium therapy has been used, especially in children.
In mild hypercalciuria (exceeding 300mg (7.5mmol)/24 hours) as well as in mild to moderate renal failure, or where there is evidence of stone formation in the urinary tract, adequate checks must be kept on urinary calcium excretion; if necessary the dosage should be reduced or calcium therapy discontinued.
High vitamin D intake should be avoided during calcium therapy, unless especially indicated.

Effervescent Calcium Gluconate Tablets BP must be used with care in patients receiving alternative compound vitamin or mineral preparations, which often contain sources of additional calcium.

Treatment should be suspended if blood calcium levels exceed 2.625-2.75mmol/litre (105-110mg/litre) or if urinary calcium excretion exceeds 5mg/kg.

This medicinal product contains 102.8 mg sodium per tablet, equivalent to 5.14% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product (20 tablets) is equivalent to 102.8% of the WHO recommended maximum daily intake for sodium. Effervescent Calcium Gluconate Tablets is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

4.5 Interaction with other medicinal products and other forms of interaction

Thiazide diuretics reduce urinary calcium excretion so the risk of hypercalcaemia should be considered.

Systemic corticosteroids reduce calcium absorption.

Patients receiving therapy with cardiac glycosides such as digoxin must not be given calcium supplements.

Oral calcium administration may reduce the absorption of oral tetracycline or fluoride preparations. An interval of three hours should be observed if the two are to be given.

4.6. Pregnancy and Lactation

The likelihood of hypercalcaemia is increased in pregnant women in whom calcium and vitamin D are co-administered. Epidemiological studies with calcium have shown no increase in the teratogenic hazard to the foetus if used in the doses recommended. Although supplemental calcium may be excreted in breast milk, the concentration is unlikely to be sufficient to produce any adverse effect on the neonate.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable effects

Mild gastrointestinal disturbances have occurred rarely (*eg* constipation, diarrhoea). Cardiac arrhythmias and bradycardia may also occur.

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 the Yellow Card Scheme; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Deliberate overdosage is unlikely due to the large size of the tablets and the necessity to dissolve the tablets in water. The symptoms of overdosage with calcium include anorexia, lassitude, nausea, vomiting, headache, extreme thirst, vertigo, and raised blood urea; calcium may be deposited in many tissues including the kidney and arteries and the plasma cholesterol level may become elevated.

Calcium intake should be reduced to a minimum and any dehydration and electrolyte imbalance corrected immediately. A loop diuretic such as furosemide may be given to increase urinary calcium excretion. Drugs (such as thiazides and vitamin D compounds) which promote hypercalcaemia should be discontinued and dietary calcium should be restricted.

If severe hypercalcaemia persists, drugs which inhibit mobilisation of calcium from the skeleton may be required. The biophosphonates are useful and disodium pamidronate is probably the most effective. Plicamycin is probably the most rapidly effective drug but cannot be given continuously for more than a few days because of marrow toxicity; the duration of its hypocalcaemic effect is unpredictable but can last several days. Corticosteroids may only be useful where hypercalcaemia is due to sarcoidosis or vitamin D intoxication; they often take several days to achieve the desired effect. Calcitonin is relatively non-toxic but its effect can wear off after a few days despite continuous use; it is rarely effective where biophosphonates have failed to reduce serum calcium adequately. In severe cases, significant amounts of calcium may be removed by peritoneal dialysis. Patients with symptoms of overdosage should avoid exposure to direct sunlight.

Special care must be exercised when treating overdosage in patients with impaired renal or hepatic function.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supplements, calcium
ATC Code: A12AA03

Calcium gluconate is used in calcium deficiency.

5.2. Pharmacokinetic Properties

Calcium is absorbed from the small intestine; about one third of ingested calcium is absorbed. Absorption decreases with age and may be more efficient when the body is deficient in calcium or from diets deficient in calcium. It is excreted in sweat, bile, pancreatic juice, saliva, urine, faeces and milk.

5.3. Pre-clinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Also contains: citric acid, magnesium stearate, povidone, saccharin sodium, sodium bicarbonate, stearic acid, tartaric acid.

6.2. Incompatibilities

None known.

6.3. Shelf Life

Shelf-life
Three years from the date of manufacture.

Shelf-life after dilution/reconstitution
Not applicable.

Shelf-life after first opening
Not applicable.

6.4. Special Precautions for Storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

The product containers are injection blow-moulded polyethylene containers and polypropylene, twist on, push down and twist off child-resistant, tamper-evident lids.
Also included in each pack is a 3g silica gel canister.

Pack sizes: 7s, 10s, 14s, 21s, 28s, 30s, 56s, 60s, 84s, 90s, 100s, 112s.
Product may also be supplied in bulk packs, for reassembly purposes only, in polybags contained in tins, skillets or polybuckets filled with suitable cushioning material. Also included are 5 x 50g silica gel bags.
Maximum size of bulk packs: 5,000.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Accord-UK Ltd
(Trading style: Accord)
Whiddon Valley
Barnstaple
Devon
EX32 8NS

8. MARKETING AUTHORISATION NUMBER(S)

PL 0142/5579 R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

11.7.86 (Product Licence of Right: 26.4.73)
19.10.97 (19.10.92)

10 DATE OF REVISION OF THE TEXT

30/01/2026