PROFESSIONAL INFORMATION
SCHEDULING STATUS
S0

1 NAME OF THE MEDICINE

CALCIUM CITRATE D (granules)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each CALCIUM CITRATE D sachet contains:

Ingredients	Per sachet
Calcium (calcium citrate)	500 mg
Vitamin D3 (cholecalciferol)	400IU

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pale yellow granules with smell and taste of orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

4.2 Posology and method of administration

One sachet daily dissolved in water, or as recommended by a healthcare provider. Wait for effervescence to subside before drinking.
The dose required is dependent on dietary calcium intake.

4.3 Contraindications

Hypersensitivity to any of the ingredients within CALCIUM CITRATE D, including any excipients.
Not for use in patients with hypercalcaemia, renal impairment, renal calculi or sarcoidosis.

4.4 Special warnings and precautions for use

- Calcium supplementation should be avoided in cases of hypercalcaemia and hypercalciuria (see **CONTRAINDICATIONS**).
- Calcium supplementation should be used with caution in patients with hypophosphatemia or hyperphosphatemia.
- Use with caution in patients with heart disease.
- CALCIUM CITRATE D contains sugar which may have an effect on the control of blood sugar in patients with *Diabetes Mellitus*. Patients with the rare hereditary condition of sorbitol intolerance should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on CALCIUM CITRATE D. The following interactions are noted from the monographs of the active ingredients:

- Calcium-channel blockers: calcium supplements may reduce the effects of calcium channel blockers.
- Digoxin: administration of high doses of calcium increases the risk of cardiac arrhythmias.
- Estrogen: concurrent use may cause hypercalcaemia.
- Thiazide diuretics: thiazides reduce calcium excretion by the kidneys.
- Thyroid medicines: Calcium can interfere with thyroid hormone replacement treatment. Separate calcium and thyroid medications by at least 4 hours.

Calcium can chelate and prevent the absorption of some medicines such as tetracyclines, quinolones, bisphosphonates, anti-retrovirals, levothyroxine and verapamil. Doses should be separated by at least 4 hours.

4.6 Fertility, pregnancy and lactation

CALCIUM CITRATE D is suitable for use during pregnancy and lactation at the recommended dose and at the discretion of a healthcare professional.

4.7 Effects on ability to drive and use machines
The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects include gastrointestinal discomfort (constipation, diarrhoea, flatulence, nausea, belching and stomach upset).

4.9 Overdose

High doses can cause nausea, vomiting, diarrhoea and symptomatic hypercalcaemia, including hypotension and bradycardia. Prolonged use of high dose of calcium (approx. 20 g/day) can cause kidney stones.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.12 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

Calcium and vitamin D are essential nutrients for the development of healthy bones and teeth.
Vitamin D helps in the absorption of calcium.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous, orange juice flavour, quinolene yellow, silicon dioxide.
Contains sugar: Sorbitol 1,7 g/sachet
Contains sweeteners: Aspartame 25 mg/sachet
Sodium cyclamate 10 mg/sachet
Sodium saccharin 5 mg/sachet

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed to protect from sunlight and moisture.
KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

CALCIUM CITRATE D sachets are packed in cartons containing 30 sachets.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION
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