Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcium Gluconate Injection BP 10% w/v, 10ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of solution contains 2.25 millimoles of Ca^{2+} as calcium gluconate (975mg/10ml).
Each ml of solution contains 0.225 millimoles of Ca^{2+} as calcium gluconate (95.7 mg/ml).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless, sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Parenteral administration is indicated where the pharmacological action of a high calcium ion concentration is required, as in acute hypocalcaemia and hypocalcaemic tetany.

4.2 Posology and method of administration

For intravenous or intramuscular injection.

Adults: The usual dose is 5 - 10ml (1.125 - 2.25 mmol or 2.25 - 4.5 mEq Ca^{++}) by slow I.V. injection or by deep I.M. injection into the gluteal region. The dose can be repeated daily or every second day as required.

Children: The usual dose is 2.5 - 5.0ml (0.562 - 1.125 mmol or 1.125 - 2.25 mEq Ca^{++}) by slow I.V. injection. The intramuscular route is not recommended for children.

Elderly: As per adults, but elderly patients should be carefully supervised (See Warnings and Precautions).

4.3 Contraindications

Use in patients with hypercalcaemia and hypercalciuria (e.g. in hyperparathyroidism, hypervitaminosis D, neoplastic disease with decalcification of bone, immobilisation osteoporosis, sarcodiosis).
Use in patients with renal insufficiency.
Use in patients with milk-alkali syndrome.

4.4 Special warnings and precautions for use

Calcium salts should be used with caution in patients with impaired renal function, or with nephrocalcinosis, or in the elderly.
Patients receiving calcium salts should be monitored, carefully, to ensure maintenance of correct calcium balance without tissue deposition. Plasma levels and urinary excretion of calcium should be monitored when high-dose

parenteral calcium is administered.
Solutions containing calcium should be administered slowly to minimise peripheral vasodilation and cardiac depression.
Extravasation should be avoided.
High Vitamin D intake should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of digoxin and other cardiac glycosides may be accentuated by calcium, resulting in serious toxicity.

4.6 Pregnancy and lactation

Calcium crosses the placenta and is excreted in breast milk and this should be borne in mind when considering the use of calcium during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Nil.

4.8 Undesirable effects

Calcium salts are irritant and can cause local reactions following intramuscular injection or if extravasation occurs during intravenous administration. Excessive amounts of calcium may lead to hypercalcaemia (See Overdose).

4.9 Overdose

Possible symptoms of hypercalcaemia include nausea, vomiting, polydipsia, polyuria, muscle weakness, bone pain, drowsiness and, in severe cases, cardiac arrhythmias and coma. If intravenous injection is too rapid, symptoms of hypercalcaemia may occur as well as a chalky taste, hot flushes and hypotension.

Treatment should be aimed at lowering the elevated plasma calcium concentration. Initial management should include rehydration and, in severe hypercalcaemia, it may be necessary to administer sodium chloride by i.v. infusion to expand the extracellular fluid. Frusemide may be administered to increase calcium excretion but thiazide diuretics should be avoided as they may increase renal absorption of calcium. Phosphates have been used to lower plasma calcium concentrations but precipitation of calcium phosphate in the tissues may result in nephrocalcinosis and impaired renal function. Haemodialysis or peritoneal dialysis may be considered where other measures have failed and where the patient remains acutely symptomatic. Serum electrolytes should be carefully monitored throughout treatment of overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium Gluconate Injection BP is a readily available source of calcium ions for the treatment of acute hypocalcaemia and hypocalcaemic tetany.

5.2 Pharmacokinetic properties

Calcium is absorbed from the small intestine. Plasma levels of calcium are normally maintained within the range 85 - 105mg per litre (2.1 - 2.6 mmol per litre). About 50% of the total plasma calcium is in the physiologically active ionised form, about 45% is bound to proteins, mainly albumin, and 5% is complexed with anions. Excretion of calcium occurs in the urine although a large proportion undergoes renal tubular reabsorption. Calcium is also excreted in the faeces.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium d-Saccharate
Water for Injections

6.2 Incompatibilities

Calcium salts can form complexes with many drugs and this may result in a precipitate. Calcium salts are incompatible with oxidizing agents, citrates, soluble carbonates, bicarbonates, phosphates, tartrates, sulphates. Physical incompatibility has also been reported with amphotericin, cephalothin sodium, cephazolin sodium, cephamandole nafate, novobiocin sodium, dobutamine hydrochloride, prochlorperazine and tetracyclines.

6.3 Shelf Life

Unopened: 3 years.

The product should be used immediately after opening.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Keep the ampoules in the outer carton.

6.5 Nature and contents of container

10 ml, clear glass ampoules, glass type I Ph. Eur. borosilicate glass, packed in cardboard cartons to contain 10 x 10 ml ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only.
Solutions containing visible solid particles should not be used.
If only part of the contents of an ampoule is used, the remaining solution should be discarded.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Ltd.
Roscrea
Co. Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 73/115/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 1988

Date of last renewal: 01 September 2003

10 DATE OF REVISION OF THE TEXT

August 2005