Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcium Acetate 500mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of Calcium Acetate.

Excipient: each tablet contains 28.15 mg of lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
A white 12.5 mm round tablet with bevelled edges and a breakline on one side.
The breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Calcium Acetate Tablets are recommended in the treatment and prevention of hyperphosphatemia in chronic renal failure particularly for patients on regular haemodialysis therapy and continuous ambulatory peritoneal dialysis.

4.2 Posology and method of administration

Hyperphosphatemia
Dosage must be determined according to the requirements of the individual patient.

Usual dose is 1-2 tablets three times daily. In special cases up to 4 tablets can be taken three times a day.

4.3 Contraindications

Hypersensitivity to calcium acetate or to any of the excipients.

Hypercalcemia and hypercalciuria.

Hypophosphataemia.

4.4 Special warnings and precautions for use

Excessive dosage may induce hypercalcemia. In patients with renal dysfunction the blood-calcium level should be monitored regularly. Should hypercalcemia occur dosage should be reduced or treatment discontinued immediately depending on the severity of the hypercalcemia. Chronic hypercalcemia may lead to vascular calcification, and other soft tissue calcification.

Patients with rare hereditary problems of galactose intolerance, the Lapp lastase deficiency or glucose – galactose malabsorption, should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Calcium interacts with several drugs: enoxacin, norfloxacin.
The absorption of antibiotics such as ciprofloxacin and tetracyclines can be affected and consequently, the intake of Calcium Acetate should be made 3 hours before or after the antimicrobal treatment.

Absorption of bisphosphonates is reduced.

Concurrent use with thiazides causes increased risk of hypercalcemia.

4.6 Fertility, pregnancy and lactation

Studies have not been done on humans or animals and problems have not been documented.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Gastro-intestinal disturbances may be experienced such as nausea, vomiting, constipation and diarrhoea.

Hypercalcaemia:
Mild hypercalcaemia (C>2.6 mmol/L) may occur in about 1% of patients and may be asymptomatic or manifest itself as constipation, anorexia, nausea and vomiting.

More severe hypercalcaemia (C>3.0 mmol/L) may occur in about 0.1% of patients and can be associated with confusion, delirium, stupor and in very severe cases coma.

Patients should be advised to consult their doctor if any of these symptoms 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Administration in excess of recommended dosage may cause severe hypercalcemia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium Acetate Tablets act as a phosphate binder in the ‘gut’, thereby preventing absorption of phosphate.

5.2 Pharmacokinetic properties

None known.

5.3 Preclinical safety data

None known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch
Lactose
Magnesium Stearate
Microcrystalline Cellulose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25ºC.
Store in original package.

6.5 Nature and contents of container

High density polyethylene or polypropylene tubs with tamper evident closures containing
50, 100, 250, 500 or 1000 tablets.
Not all pack sizes may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited,
Ballymacarbry,
Clonmel,
Co. Tipperary.

8 MARKETING AUTHORISATION NUMBER

PA0281/063/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:	23 January 1998
Date of last renewal:	23 January 2008

10 DATE OF REVISION OF THE TEXT

May 2015