Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ostram 1.2 g.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 3.30 g of Tricalcium Phosphate Ph. Eur. equivalent to 1.2 g of calcium in a formulation as described in the application.

3 PHARMACEUTICAL FORM

Powder for oral suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To correct calcium deficiency states and maintain appropriate balance in such disorders as osteoporosis, osteomalacia, rickets, tetany, malabsorption states. This may be used if necessary provided expert advice is sought in pregnancy and lactation.

4.2 Posology and method of administration

Oral

Recommended dosage: 1 sachet a day.

4.3 Contraindications

Use in patients with hypercalcaemia and hypercalciuria such as hyperparathyroidism, hypervitaminosis D, neoplastic diseases with decalcification of bone, immobilisation osteoporosis, sarcoidosis.

Use in patients with renal insufficiency.

Use in the 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.

The use of calcium salts should be accompanied by a careful surveillance to ensure maintenance of correct calcium balance.

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 and toxicity may be produced.

Calcium salts should not be administered simultaneously with tetracycline because of reduced absorption of anti-infective.

4.6 Pregnancy and lactation

See section 4.1, Therapeutic indications

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

With prescribed dose side effects minimal but with overdose or inappropriate usage *see section 4.9, Overdose.*

4.9 Overdose

Symptoms include thrist, polyurea, vomiting, dehydration, hypertension, vasomotor symptoms and constipation.

Treatment
Stop vitamin D and calcium supplements, rehydrate. Other measures include use of diuretics, steroids. Calcitonin (or dialysis) to reduce excess calcium.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium saccharin, Lime (flavour), Carboxymethylcellulose sodium.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf life expiry date for this product shall not exceed 2 years from the date of its manufacture.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

A paper-polyethylene-aluminium sachet containing a white powder which upon reconstitution with water forms a white cloudy suspension with a lime flavour.

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

Pour the content of the sachet into approximately half a glass of water and shake until a homogenous suspension is obtained.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA0656/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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