Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcichew 500mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet of 500 mg contains calcium carbonate equivalent to 500 mg calcium.Excipients with known effect: Isomalt (E953) – 62 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet.

Round, white, uncoated and convex tablet. May have small specks.

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 and in pregnancy and lactation.

As a phosphate binding agent in the management of renal failure in patients on renal dialysis.

4.2 Posology and method of administration

Posology

Adults:
Adjunctive therapy in osteoporosis: 2 to 3 tablets daily.

Prevention and treatment of calcium deficiency: 2 to 3 tablets daily.

Phosphate binder: Dose as required by the individual patient depending on serum phosphate level.

Special patient populations

Elderly patients:
Dosage as for adults.

Paediatric patients:
Prevention and treatment of calcium deficiency: 2 to 3 tablets daily.

Phosphate Binder: Dose as required by the individual patient depending on serum phosphate level.

Impaired renal function:
In patients with severe renal failure having a creatinine clearance of less than 30 ml/minute, dosage adjustments may be necessary dependent on serum calcium levels. See section 4.4.

Impaired hepatic function:
No dose adjustment is required.

Method of administration
Oral.

The tablets should be chewed or sucked.

For phosphate binding, the tablets should be taken just before, during or just after each meal in order to bind phosphate in the food.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria.
- Renal calculi (nephrolithiasis)

4.4 Special warnings and precautions for use

In renal insufficiency the tablets should be given only under controlled conditions for hyperphosphataemia. Caution should be exercised in patients with a history of renal calculi.

Monitoring is especially important in patients on concomitant treatment with cardiac glycosides or diuretics (see section 4.5),

During high dose therapy and especially during concomitant treatment with vitamin Dand/or medications or nutrients (such as milk) containing calcium, there is a risk of hypercalcaemia and milk-alkali syndrome (hypercalcaemia, alkalosis and renal impairment) with subsequent kidney function impairment. In these patients, serum calcium levels should be monitored and renal function should be monitored.

Calcichew 500 mg Chewable Tablets contain isomalt (E953). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interactions

Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations.

For this reason, tetracycline preparations should be administered at least two hours before, or four to six hours after, oral intake of calcium.

Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.

If a bisphosphonate is used concomitantly, this preparation should be administered at least three hours before the intake of Calcichew 500mg Chewable Tablets since gastrointestinal absorption may be reduced.

The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours.

The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or after intake of calcium.

Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken two hours before or after calcium carbonate.

4.6 Fertility, pregnancy and lactation

Pregnancy

Calcichew 500mg Chewable Tablets can be used during pregnancy. Daily intake should not exceed 2500 mg of calcium as permanent hypercalcaemia has been related to adverse effects on the developing foetus.

Breastfeeding

Calcium carbonate can be used during breast-feeding. Calcium passes into breast milk but at therapeutic doses no effects on the breastfed new-born are anticipated.

4.7 Effects on ability to drive and use machines

Calcium carbonate has no known influence on ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), or very rare (<1/10,000).

Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.
Very rare: Milk-alkali syndrome (frequent urge to urinate; continuing headache; continuing loss of appetite; nausea or vomiting; unusual tiredness or weakness; hypercalcaemia, alkalosis and renal impairment). Seen usually only in overdose (see section 4.9).

Gastrointestinal disorders
Rare: Constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea.

Skin and subcutaneous tissue disorders
Very rare: Pruritus, rash and urticaria.

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 to 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

Overdose can lead to hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, nephrolithiasis and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification.

Milk-alkali syndrome (may occur in patients who ingest large amounts of calcium and absorbable alkali.

Treatment of hypercalcaemia: The treatment with calcium must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, vitamin D and cardiac glycosides must also be discontinued. Treatment: rehydration, and, according to severity of hypercalcaemia, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supplements; Calcium.

ATC-code: A12AA04

An adequate intake of calcium is of importance during growth, pregnancy and breast-feeding.

5.2 Pharmacokinetic properties

Absorption: The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose.

Distribution and biotransformation: 99% of the calcium in the body is concentrated in the hard structure of bones and teeth. The remaining 1% is present in the intra- and extracellular fluids. About 50% of the total blood-calcium content is in the physiologically active ionised form with approximately 10% being complexed to citrate, phosphate or other anions, the remaining 40% being bound to proteins, principally albumin.

Excretion and elimination: Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.

5.3 Preclinical safety data

There is no information of relevance to the safety assessment in addition to what is stated in other parts of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E967)
Povidone
Magnesium stearate
Sucralose (E955)
Isomalt (E953)
Flavouring (orange)
Mono, di-fatty acid glycerides

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C.

Keep the container tightly closed to protect from moisture.

6.5 Nature and contents of container

HDPE container with screw cap containing 100 tablets.

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

Takeda Products Ireland Ltd
6th Floor
South Bank House
Barrow Street
Dublin 4
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2229/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 1993
Date of last renewal: 20th December 2008

10 DATE OF REVISION OF THE TEXT

June 2020