SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calcomben 500 mg/ 400 IU chewable tablet
Calcomben 500 mg/ 800 IU chewable tablet
Calcomben 1000 mg/ 800 IU chewable tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcomben 500 mg/ 400 IU chewable tablet
Each tablet contains calcium carbonate equivalent to 500 mg calcium and 10 microgram cholecalciferol equivalent to 400 IU vitamin D_3

Excipient(s) with known effect:
Each tablet contains sucrose 0.7 mg, sodium 3.5 mg

Calcomben 500 mg/ 800 IU chewable tablet
Each tablet contains calcium carbonate equivalent to 500 mg calcium and 20 microgram cholecalciferol equivalent to 800 IU vitamin D_3

Excipient(s) with known effect:
Each tablet contains sucrose 1.4 mg, sodium 3.6 mg

Calcomben 1000 mg/ 800 IU chewable tablet
Each tablet contains calcium carbonate equivalent to 1000 mg calcium and 20 microgram cholecalciferol equivalent to 800 IU vitamin D_3

Excipient(s) with known effect:
Each tablet contains sucrose 1.4 mg, sodium 7.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet

Calcomben 500 mg/ 400 IU chewable tablet
White to off white, round, uncoated and biconvex tablets of 14 mm, engraved with E4 on one side. May have small specks.

Calcomben 500 mg/ 800 IU chewable tablet
White to off white, round, uncoated and biconvex tablets of 14 mm, engraved with E5 on one side. May have small specks.

Calcomben 1000 mg/ 800 IU chewable tablet
White to off white, round, uncoated and biconvex tablets of 18 mm. May have small specks.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of calcium and vitamin D deficiency in elderly people.
Vitamin D and calcium supplement in addition to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency.

4.2 Posology and method of administration

Posology

Adults and elderly

500 mg/400 IU tablet: 2 tablets daily

500 mg/ 800 IU tablet: 1 tablet daily

1000 mg/ 800 IU tablet: 1 tablet daily

Dosage in hepatic impairment
No dose adjustment is required.

*Dosage in renal impairmen*t
Calcomben should not be used in patients with severe renal impairment (see section 4.3).

Paediatric population
Calcomben is not intended for use in children.

Method of administration
Oral. The tablet should be chewed, never swallowed whole.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Severe renal impairment (glomerular filtration rate < 30 ml/min/1.73m^2)
- Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria
- Renal calculi (nephrolithiasis)
- Hypervitaminosis D

4.4 Special warnings and precautions for use

During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics (see section 4.5) and in patients with a high tendency to calculus formation. In case of hypercalcaemia or signs of impaired renal function the dose should be reduced or the treatment discontinued.

Calcium carbonate with cholecalciferol tablets should be used with caution in patients with hypercalcaemia or signs of impaired renal function and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account.

During concomitant treatment with other sources of vitamin D and/or medications or nutrients (such as milk) containing calcium, there is a risk of hypercalcaemia and milk-alkali syndrome with subsequent kidney function impairment. In these patients serum calcium levels should be followed and renal function should be monitored.

Calcomben should be prescribed with caution to patients suffering from sarcoidosis due to risk of increased metabolism of vitamin D into its active form. These patients should be monitored with regard to the calcium content in serum and urine.

Calcomben tablets should be used cautiously in immobilised patients with osteoporosis due to increased risk of hypercalcaemia.

Paediatric population
Calcomben tablets are not intended for use in children.

Calcomben contains sucrose
Calcomben 500 mg/ 400 IU tablet contains 0.7 mg sucrose, Calcomben 500 mg/ 800 IU tablet and Calcomben 1000 mg/ 800 IU tablets contains 1.4 mg sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Calcomben contains Sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

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 and vitamin D. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.

If a bisphosphonate or sodium fluoride is used concomitantly, this preparation should be administered at least three hours before the intake of Calcomben 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 six hours 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 at least two hours before or after Calcomben.

Treatment with orlistat may potentially impair the absorption of fat-soluble vitamins (e.g. vitamin D_3).

Calcium decreases exposure (AUC, Cmax) of HIV integrase inhibitors (such as ritonavir, dolutegravir, raltegravir, elvitegravir) by chelation if co-administered. Please advise the product information of the specific HIV integrase inhibitor in use for further guidance.

4.6 Fertility, pregnancy and lactation

Pregnancy
Calcomben can be used during pregnancy, in case of a calcium and vitamin D deficiency. During pregnancy the daily intake should not exceed 2500 mg calcium and 4000 IU vitamin D. Studies in animals have shown reproductive toxicity of high doses of vitamin D (see section 5.3). In pregnant women, overdoses of calcium and vitamin D should be avoided as permanent hypercalcaemia has been related to adverse effects on the developing foetus.
A large amount of data on pregnant women (more than 1000 exposed outcomes) indicates no malformative nor feto/ neonatal toxicity for vitamin D and calcium at therapeutic doses.

Breastfeeding
Calcium and vitamin D_3 pass into the breast-milk and an overdose has to be avoided in the infant. This should be considered when giving additional vitamin D to the child. A decision must be made whether to discontinue breast-feeding or to discontinue Calcomben or adjust therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
Normal endogenous levels of calcium and vitamin D_3 are not expected to have any adverse effects on fertility.

4.7 Effects on ability to drive and use machines

Calcomben has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions frequencies are defined as:

Very common (≥1/10)
Common (≥1/100 to<1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Immune system disorders
Not known: Hypersensitivity reactions such as angio-oedema or laryngeal oedema.

Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.
Very rare: Seen usually only in overdose (see section 4.9) Milk-alkali syndrome.

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

Skin and subcutaneous disorders
Rare: Pruritus, rash and urticaria.

Patients with renal impairment are at potential risk of hyperphosphatemia, nephrolithiasis and nephrocalcinosis. See section 4.4.

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 the national reporting system listed in Appendix V.*

4.9 Overdose

Overdose can lead to hypervitaminosis and hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, renal calculi 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. Symptoms are frequent urge to urinate, continuing headache, continuing loss of appetite, nausea or vomiting, unusual tiredness or weakness, hypercalcaemia, alkalosis and renal impairment.

Treatment of hypercalcaemia: The treatment with calcium and vitamin D must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, vitamin D and cardiac glycosides must also be discontinued. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids. 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: Calcium combinations with vitamin D and/or other drugs, ATC code: A12AX

Vitamin D increases the intestinal absorption of calcium.

Administration of calcium and vitamin D_3 counteracts the increase of parathyroid hormone (PTH)

which is caused by calcium deficiency and which cause increased bone resorption.

A clinical study of institutionalised patients suffering from vitamin D deficiency indicated that a daily intake of two tablets of calcium 500 mg/vitamin D 400 IU for six months normalised the value of the 25-hydroxylated metabolite of vitamin D_3 and reduced secondary hyperparathyroidism and alkaline phosphatases.

An 18 month double-blind, placebo controlled study including 3270 institutionalised women aged 84+/- 6 years who received supplementation of vitamin D (800 IU/day) and calcium phosphate (corresponding to 1200 mg/day of elemental calcium), showed a significant decrease of PTH secretion. After 18 months, an "intent-to treat" analysis showed 80 hip fractures in the calcium-vitamin D group and 110 hip fractures in the placebo group (p=0,004). A follow-up study after 36 months showed 137 women with at least one hip fracture in the calcium-vitamin D group (n=1176) and 178 in the placebo group (n=1127) (p<0,02).

5.2 Pharmacokinetic properties

Calcium
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.

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

Vitamin D
Absorption: Vitamin D is easily absorbed in the small intestine.

Distribution and biotransformation: Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Vitamin D which is not metabolised is stored in adipose and muscle tissues.

Metabolism: Cholecalciferol is converted in the liver by hydroxylation to the active form 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25- hydroxycholecalciferol. 1,25-hydroxycholecalciferol is the metabolite responsible for increasing calcium absorption.

Elimination: Vitamin D is excreted in faeces and urine.

5.3 Preclinical safety data

At doses far higher than the human therapeutic range teratogenicity has been observed in animal studies. There is further no information of relevance to the safety assessment in addition to what is stated in other parts of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E967)
Sucrose
Medium chain triglycerides
Silicon dioxide
DL-alpha-tocopherol
Modified food starch
Sucralose (E955)
Povidone
Citric acid
Sodium ascorbate
Croscarmellose sodium
Flavoring (lemon) containing sucrose
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

1 year

6.4 Special precautions for storage

This medicinal product does not require any special storage condition.

6.5 Nature and contents of container

Calcomben 500 mg/400 IU
60, 90, 100, 120, 180 and 200 tablets in polyethylene bottles with polyethylene liner/polypropylene cap.

Calcomben 500 mg/800 IU and Calcomben 1000 mg/800 IU
30, 60, 90 and 100 tablets in polyethylene bottles with polyethylene liner/polypropylene cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

EQL Pharma AB
Stortorget 1
222 23 Lund
Sweden

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2026-04-16