SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Kalcipos-D 500 mg/ 800 IU chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains calcium carbonate equivalent to 500 mg calcium, cholecalciferol (Vitamin D_3) 800 IU (20 microgram).

Excipients with known effect: glucose 200 mg and sucrose 1.8 mg.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
White to off white, round, engraved R152 on one side, diameter 17 mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Kalcipos-D chewable tablets is indicated in adults aged 18 years and over.

4.2 Posology and method of administration

Posology

Adults and older people
One chewable tablet (500 mg/800 IU) daily.

The amount of calcium in Kalcipos-D is less than the usually recommended daily intake.
Kalcipos-D is therefore primarily to be used by patients with need of D-vitamin substitution but with a dietary intake of calcium of 500 mg-1000 mg per day. The patients dietary intake of calcium should be estimated by the prescriber.

Hepatic impairment
No dose adjustment is required

Renal impairment
Kalcipos-D should be used with caution in patients with renal impairment (see section 4.4).

Paediatric population
There is no relevant use of Kalcipos-D chewable tablets in children or adolescents.

Method of administration
Tablet can be chewed or slowly melted in the mouth.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Hypercalciuria and hypercalcaemia and diseases and/or conditions which lead to hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism).
- Nephrolithiasis.
- Nephrocalcinosis
- Hypervitaminosis D.
- Renal failure.

4.4 Special warnings and precautions for use

Sarcoidosis

Calcium/cholecalciferol chewable tablets 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.

Monitoring of calcium levels

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. If signs of hypercalcaemia and/or hypercalciuria occur treatment must be discontinued. Treatment should be reduced or temporarily stopped if urinary calcium levels exceed 7.5mmol/24 h (300 mg/24 h) in adults.

Renal impairment

This product should be used with caution in patients with renal impairment and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal impairment, vitamin D in the form of cholecalciferol might not be activated normally. The physician may decide if other forms of vitamin D should be supplemented (see section 4.2).

Osteoporosis

Calcium/cholecalciferol chewable tablets should be used with caution in immobilised patients with osteoporosis due to increased risk of hypercalcaemia.

Vitamin D therapy

The content of vitamin D (800 IU) in calcium/cholecalciferol chewable tablets should be considered when prescribing other medicinal products containing vitamin D. Additional doses of calcium or vitamin D should be taken under close medical supervision. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently.

Milk-alkali syndrome (Burnett´s syndrome) i.e. hypercalcaemia, alkalosis and renal impairment, can develop when large amounts of calcium are ingested with absorbable alkali.

Co-administration with tetracyclines or quinolones is usually not recommended, or must be done with precaution (see section 4.5).

Kalcipos-D chewable tablets contain glucose and sucrose.

Kalcipos-D chewable tablets contains glucose and 1.8 mg sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The content of glucose and sucrose may be harmful to the teeth.

Sodium content

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
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.

Phenytoin / barbiturates
Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D_3 since the metabolism increases.

Corticosteroids
Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of Kalcipos-D.

Cardiac glycosides
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.

Estramustine
Calcium reduces the gastrointestinal absorption of estramustine by formation of an insoluble complex. Consequently, administration of Kalcipos-D and estramustine containing products should be separated by at least two hours.

Levothyroxine
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.

Iron / zinc / strontium ranelate preparations
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 Kalcipos-D.

Bisphosphonates / sodium fluoride
If a bisphosphonate is used concomitantly, this preparation should be administered at least one hour before the intake of Kalcipos-D since gastrointestinal absorption may be reduced.

Calcium may also reduce absorption of sodium fluoride and such preparations should be administered at least three hours before the intake of Kalcipos-D.

Ion-exchange resins / laxatives

Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.

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

Tetracyclines
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.

Quinolone antibiotics
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.

Oxalic acid / phytic acid
Oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption through formation of insoluble compounds with calcium ions. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid.

4.6 Fertility, pregnancy and lactation

Pregnancy

Studies in animals have shown reproductive toxicity of high doses of vitamin D (see 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. In healthy pregnant women, the daily intake of supplemental calcium and vitamin D should not exceed 1500 mg calcium and 600 IU vitamin D.

Kalcipos-D is therefore not indicated for routine prophylaxis of calcium and vitamin D deficiency in pregnancy, but can be used in pregnant women who are at high risk of developing hypocalcaemia, or who already suffer from a calcium and vitamin D deficiency.

Breast-feeding

Kalcipos-D can be used during breast-feeding. Calcium and vitamin D_3 pass into breast milk. This should be considered when giving additional vitamin D to the child.

Fertility

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

4.7 Effects on ability to drive and use machines

Kalcipos-D 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) or not known (cannot be estimated from the available data)

Immune system disorders
Not known (cannot be estimated from the available data): Hypersensitivity reactions such as angioedema or laryngeal oedema.

Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.
Very rare: Milk-alkali syndrome, seen usually only in overdose.

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

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

Special Populations
Patients with renal impairment are at potential risk of hyperphosphataemia, nephrolithiasis and nephrocalcinosis.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 1000 mg calcium and 800 IU vitamin D for six months normalised the value of the 25-hydroxylated metabolite of vitamin D3 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).

5.2 Pharmacokinetic properties

Calcium

Absorption: The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose. The bioavailability of calcium can be slightly increased by concomitant intake of food.

Distribution: 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.

Biotransformation: 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: 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.

Biotransformation: 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- dihydroxycholecalciferol. 1,25-dihydroxycholecalciferol is the metabolite responsible for increasing calcium absorption.

Elimination: Vitamin D is excreted in faeces and urine.

5.3 Preclinical safety data

At vitamin D3 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

Liquid spray dried glucose
Magnesium stearate
Sodium citrate
Xylitol
all-*rac*-alfa-tocoferol
Acacia
Sodium laurilsulphate
Sucrose
Medium chain triglycerides
Starch sodium octenyl succinate (E1450)
Silicon dioxide
Sodium ascorbate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life: 3 years

Shelf life after first opening container: 6 months

6.4 Special precautions for storage

Store below 25°C. Store in the original package, in order to protect from light.
Keep container tightly closed in order to protect from moisture.
For storage conditions after first opening of medicinal product, see section 6.3

6.5 Nature and contents of container

20, 30,40,50,60, 90, 100 and 180 chewable tablets in plastic containers of HDPE with screw caps made of HDPE.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Cooper Consumer Health B.V.,

Verrijn Stuartweg 60,

1112 AX Diemen,

The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

PL 60682/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25-01-2010
Date of last renewal: 22-12-2014

10 DATE OF REVISION OF THE TEXT

15/07/2025