# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Calcium Carbonate / Colecalciferol 1250mg / 400IU chewable tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains

Calcium Carbonate 1250mg (equivalent to Calcium 500mg)

Colecalciferol as Colecalciferol Concentrate (Powder Form) 400 IU (equivalent to Vitamin D3 10micrograms).

Excipients with known effect: Aspartame (E951), Sorbitol (E420), and Sucrose (part of the Vitamin D3 concentrate: approximately 0.8 milligrams per tablet).

For the full list of excipients, see Section 6.1

## 3 PHARMACEUTICAL FORM

Chewable Tablet

White to off white coloured, circular biconvex chewable tablet debossed with ‘BP’ on one side and ‘4’ on the other side.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Tablets should be used only as a therapeutic and not as a food supplement when the diet is deficient or when normal requirement of both components is increased.

Tablets may be used as an adjunct to specific therapy for osteoporosis or as a therapeutic supplement in established osteomalacia, pregnant patients at high risk of needing such a therapeutic supplementation or malnutrition when dietary intake is less than that required.

## 4.2 Posology and method of administration

Oral.

Adults and elderly and children over 12 years of age:

Two chewable tablets per day, preferably one tablet each morning and evening.

Children:

Not recommended for children under 12 years.

## 4.3 Contraindications

Absolute contra-indications are hypercalcaemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and vitamin D overdosage. Severe renal failure. Hypersensitivity to any of the tablet ingredients.

Relative contra-indications are osteoporosis due to prolonged immobilisation, renal stones, and severe hypercalciuria.

## 4.4 Special warnings and precautions for use

Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully including periodic checks of plasma calcium levels and urinary calcium excretion.

In patients with a history of renal stones urinary calcium excretion should be measured to exclude hypercalciuria.

With long-term treatment it is advisable to monitor serum and urinary calcium levels and kidney function, and reduce or stop treatment temporarily if urinary calcium exceeds 7.5mmol/24 hours (300mg/24 hours).

Caution is required in patients receiving treatment for cardiovascular disease (see Section 4.5 – thiazide diuretics and cardiac glycosides including digitalis).

Calcium Carbonate and Cholecalciferol Chewable Tablets should also be used with caution in other patients with increased risk of hypercalcaemia e.g. patients with sarcoidosis or those suffering from malignancies.

This medicinal product contains Sorbitol and Sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Allowances should be made for calcium and vitamin D supplements from other sources.

## 4.5 Interaction with other medicinal products and other forms of interaction

The risk of hypercalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion. Hypercalcaemia must be avoided in digitalised patients.

Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium.

Concomitant treatment with phenytoin or barbiturates can decrease the effect of vitamin D because of metabolic activation. Concomitant use of glucocorticoids can decrease the effect of vitamin D.

The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with vitamin D. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium.

Calcium salts may reduce the absorption of thyroxine, bisphosphonates, sodium fluoride, quinolone or tetracycline antibiotics or iron. It is advisable to allow a minimum period of four hours before taking the calcium.

## 4.6 Fertility, Pregnancy and lactation

**Pregnancy**

During pregnancy treatment with Calcium Carbonate and Cholecalciferol chewable tablets should always be under the direction of a physician and requirements for calcium and vitamin D are increased but in deciding on the required supplementation allowances should be made for availability of these agents from other sources. If Calcium Carbonate and Cholecalciferol chewable tablets and iron supplements are both required to be administered to the patient, they should be taken at different times (see Section 4.5).

**Breast feeding**

In humans, long term hypercalcaemia can lead to physical and mental retardation, aortic stenosis and retinopathy in a new born child. Vitamin D and its metabolites pass into the breast milk.

**Fertility**

Overdoses of vitamin D have shown teratogenic effects in pregnant animals. However, there have been no studies on the use of this medicinal product in human fertility.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

The use of calcium supplements has, rarely, given rise to mild gastro-intestinal disturbances, such as constipation, flatulence, nausea, gastric pain, diarrhoea. Following administration of vitamin D supplements occasional skin rash has been reported.

Hypercalciuria, and in rare cases, hypercalcaemia have been seen with long term treatment at high dosages.

**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.

## 4.9 Overdose

The most serious consequence of acute or chronic overdose is hypercalcaemia due to vitamin D toxicity. Symptoms may include nausea, vomiting, polyuria, anorexia, weakness, apathy, thirst and constipation. Chronic overdoses can lead to vascular and organ calcification as a result of hypercalcaemia. Treatment should consist of stopping all intake of calcium and vitamin D and rehydration.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: A12AX01 Calcium Carbonate and Colecalciferol

Strong evidence that supplemental calcium and vitamin D3 can reduce the incidence of hip and other non-vertebral fractures derives from an 18 month randomised placebo controlled study in 3270 healthy elderly women living in nursing homes or apartments for elderly people. A positive effect on bone mineral density was also observed.

In patients treated with 1200mg elemental calcium and 800IU vitamin D3 daily, i.e. the same dose delivered by two tablets of Calcium Carbonate and Colecalciferol chewable tablets, the number of hip fractures was 43% lower ($p=0.043$) and the total number of non vertebral fractures was 32% lower than among those who received placebo. Proximal femur bone mineral density after 18 months of treatment increased 2.7% in the calcium/vitamin D3 group and decreased 4.6% in the placebo group ($p < 0.001$). In the calcium/vitamin D3 group, the mean serum PTH concentration decreased by 44% from baseline at 18 months and serum 25-hydroxy-vitamin D concentration had increased by 162% over baseline.

Analysis of the intention-to-treat results showed a decreased probability of both hip fractures ($p = 0.004$) and other fractures ($p < 0.001$) in the calcium/vitamin D3 treatment group. Analysis of the other two populations (active treatment and those

treated and followed for 18 months) revealed comparable results to the intention-to-treat analysis.

The odds ratio for hip fractures among women in the placebo group compared with those in the calcium/vitamin D3 group was 1.7 (95% CI 1.0 to 2.8) and that for other nonvertebral fractures was 1.4 (95% Cl 1.4 to 2.1). In the placebo group, there was a marked increase in the incidence of hip fractures over time whereas the incidence in the calcium/vitamin D3 group was stable. Thus treatment reduced the age-related risk of fracture at 18 months ($p = 0.007$ for hip fractures and $p = 0.009$ for all non-vertebral fractures). At 3 years follow-up, the decrease in fracture risk was maintained in the calcium/vitamin D3 group.

### 5.2 Pharmacokinetic properties

The pharmacokinetic profiles of calcium and its salts are well known. Calcium carbonate is converted to calcium chloride by gastric acid. Calcium is absorbed to the extent of about 15-25% from the gastro-intestinal tract while the remainder reverts to insoluble calcium carbonate and calcium stearate, and is excreted in the faeces.

The pharmacokinetics of vitamin D is also well known. Vitamin D is well absorbed from the gastro-intestinal tract in the presence of bile. It is hydroxylated in the liver to form 25-hydroxycolecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25 dihydroxycolecalciferol (calcitriol). The metabolites circulate in the blood bound to a specific α-globin. Vitamin D and its metabolites are excreted mainly in the bile and faeces.

### 5.3 Preclinical safety data

Calcium Carbonate and Vitamin D are well known and widely used materials and have been used in clinical practice for many years.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Starch Pregelatinized
Povidone K30
Aspartame (E951)
Xylitol
Mannitol (E421)
Sorbitol (E420)
Magnesium Stearate

DL-α-tocopherol
Modified Food Starch
Triglycerides of medium chain fatty acids
Sodium Ascorbate Crystalline
Sucrose
Colloidal anhydrous silica,
Lemon flavour (contains Maize Maltodextrin, Acacia Gum, Alpha Tocopherol)

### 6.2 Incompatibilities

Not Applicable

### 6.3 Shelf life

24 Months

### 6.4 Special precautions for storage

Do not store above 25°C. Store in the original container / package in order to protect from moisture.

### 6.5 Nature and contents of container

100 tablets in Clear PVC/PVdC-Alu Blister pack.
60 tablets in HDPE container.

### 6.6 Special precautions for disposal

No special conditions.

## 7 MARKETING AUTHORISATION HOLDER

Blue Bio Pharma (UK) Limited,

Office 3.05, 1 King Street,

London, United Kingdom, EC2V 8AU

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 53594/0006

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/01/2025

## 10 DATE OF REVISION OF THE TEXT

29/01/2025