SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calcium and Ergocalciferol Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains calcium lactate pentahydrate 300 mg, calcium phosphate 150 mg and ergocalciferol 400 i.u

Excipients with known effect:
Each tablet contains Lactose 159 mg and Sucrose 0.12 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.

White, circular, normal convex tablet, engraved with Company logo on one side and A021 on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of calcium and vitamin D deficiency.

4.2 Posology and method of administration

Posology

Adults
Normal deficiency: One tablet daily.
Severe deficiency: Higher doses may be necessary, as directed by the physician.

The elderly
Do not use in the elderly without medical advice.

Children
Over 12 years of age: As directed by the physician.

Under 12 years of age: Not recommended.

Method of administration
Oral.

4.3 Contraindications

Hypersensitivity to the actives substances or to any of the excipients listed in Section 6.1.

Hypercalcaemia, hypercalciuria, renal calculi, renal function impairment, sarcoidosis, hypoparathyroidism and metastatic calcification.

4.4 Special warnings and precautions for use

Risk-benefit should be considered in the following medical conditions: dehydration,
electrolyte imbalance, diarrhoea or chronic gastro-intestinal malabsorption.

Hypercalcaemic effect should be borne in mind when prescribing these tablets and the
role of the liver and kidney on the different forms of vitamin D.

Plasma-calcium concentrations should be monitored at intervals and whenever nausea or vomiting occurs, or in renal impairment and in patients receiving high doses.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use with:

- excessive amounts of alcohol, caffeine or tobacco decreases calcium absorption.
- fibre, oxalates, phytates may reduce calcium absorption.
- calcitonin may antagonise the effect of calcitonin in the treatment of hypercalcaemia.
- *Other calcium and magnesium-containing medications:* may increase serum calcium or magnesium concentrations leading to hypercalcaemia or hypermagnesemia respectively.
- cellulose sodium phosphate may decrease effectiveness of cellulose sodium phosphate.
- oestrogens or oestrogen-containing oral contraceptives may increase calcium absorption.

- Thiazides: there is an increased risk that hypercalcaemia may develop when calcium and ergocalciferol is given in combination with thiazides (eg. hydrochlorothiazide, chlorothiazide, bendroflumethiazide) and also with chlortalidone, indapamide, metolazone.

- Digoxin and other cardiac glycosides: their effects may be enhanced by calcium, especially in combination with ergocalciferol, and may precipitate digitalis intoxication.

- etidronate may prevent absorption of etidronate.

- Calcium lactate *decreases the absorption of the following*: iron, tetracyclines, zinc, dolutegravir, eltrombopag, estramustine.

- *Phenytoin:* decreases the bioavailability of both phenytoin and calcium.

- potassium phosphates or potassium and sodium phosphates may increase the potential for deposition of calcium in soft tissues if serum ionized calcium is high

- sodium fluoride may cause them to complex and inhibit absorption of both fluoride and calcium.

- *Vitamin A:* more than 5,000 iu Vitamin A per day may stimulate bone loss and counteract the effects of calcium supplementation.

- Large doses of Vitamin D, especially calcifediol and calcitriol may increase intestinal absorption of calcium, increasing risk of chronic hypercalcaemia.

- Vitamin D activity may be reduced in patients taking barbiturates or anticonvulsants concomitantly. Phenobarbitone and primidone decrease the effect of erogacalciferol.

4.6 Fertility, pregnancy and lactation

Pregnancy
The tablets should not be used in the second and third trimester of pregnancy.

Breast-feeding
Should not be used while breast-feeding as it may cause hypercalcaemia in the infant, since calcium is excreted in the breast milk.

In the neonate problems in nursing babies have not been documented.

4.7 Effects on ability to drive and use machines

No or negligible effect

4.8 Undesirable effects

Undesirable effects are more likely if larger than recommended doses are taken, if taken for a longer period of time or if taken by patients with renal function impairment.

The following are undesirable effects with frequency unknown (cannot be estimated from the available data):

Hypercalcaemia may occur. Constipation, drowsiness, headache, loss of appetite, unusually dry mouth, tiredness or weakness are early signs of hypercalcaemia.

Additional effects of either calcium or ergocalciferol can be abdominal pain, constipation, diarrhoea, nausea, vomiting, weight loss, hypercalciuria, arrhythmia, asthenia, myalgia.

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

Hypercalcaemia may occur with prolonged high doses / overdose.

Symptoms
Late signs of hypercalcaemia are confusion, high blood pressure, increased thirst, irritability, irregular or slow heart beat, mental depression, muscle or bone pain, nausea and vomiting, frequency of urination.
Nausea, vomiting, diarrhoea, polyuria, sweating, depression and headache may occur.

Management
If signs of hypercalcaemia are seen then treatment should be stopped.

Severe hypercalcaemia should be actively treated with an iv infusion of sodium chloride 0.9%; a loop diuretic may be given to increase urinary calcium excretion. If this fails, calcitonin may be administered by injection, or alternatively, bisphosphonates or corticosteroids may be used. Phosphate infusion must not be given due to the danger of metastatic calcification. In severe cases, significant amounts of calcium may be removed by peritoneal dialysis. Patients with symptoms of overdosage should avoid exposure to direct sunlight. Special care must be exercised when treating overdosage in patients with impaired renal function.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group:
ATC Code: A12AX – Calcium, Combinations with Vitamin D and/or other drugs.

CALCIUM

Calcium is essential for the functional integrity of the nervous, muscular and skeletal systems. It plays a role in normal cardiac function, renal function, respiration, blood coagulation, and cell membrane and capillary permeability. Also, calcium helps to regulate the release and storage of neurotransmitters and hormones, the uptake and binding of amino acids, absorption of Vitamin B12 and gastrin secretion. The calcium of bone is in a constant exchange with the calcium of plasma. Since the metabolic functions of calcium are essential for life, when there is a disturbance in the calcium balance because of dietary deficiency or other causes, the stores of calcium in bone may be depleted to fill the body's more acute needs.

ERGOCALCIFEROL

Ergocalciferol is an antirachitic substance obtained from ergosterol by ultraviolet irradiation. It takes slightly longer to act than dihydrotachysterol and its effects last longer. It has cumulative action and dosage must be carefully controlled. The effects of changes in dosage may not be apparent for about six weeks. It is necessary for the absorption of calcium and phosphate from the gastro-intestinal tract and for their transport. Deficiency results in rickets in children and osteomalacia in adults and is a factor in the production of tetany

5.2 Pharmacokinetic properties

CALCIUM

Approximately one-fifth to one-third of orally administered calcium is absorbed in the small intestine, depending on the presence of Vitamin D metabolites, pH in lumen, amount of protein in diet, and on dietary factors, such as calcium binding to fibre, phytates or oxalates.

80% of calcium is eliminated in faeces, and small amounts are excreted in the urine, varying directly with degree of calcium absorption. Absorption decreases with age and may be more efficient when the body is deficient in calcium or from diets deficient in calcium. It is excreted in sweat, bile, pancreatic juice, saliva, urine, faeces and milk.

ERGOCALCIFEROL

Calciferol is absorbed through the gastro intestinal tract and is hydroxylated in the liver to 25-hydroxycholecalciferol, the most abundant form in the circulation. It is subjected to enterohepatic circulation and is hydroxylated to 1,25-dihydroxy-cholecalciferol in the renal tubule cells, this production being regulated by the concentration 1,25-dihydroxycholecalciferol, parathyroid hormone, calcium phosphate and prolactin in the circulation. 1,25-dihydroxycholecalciferol is the active metabolite of Vitamin D and is considered to be hormonal.

The metabolism of ergocalciferol has been less extensively studied than that of cholecalciferol but is believed to be similar. Vitamin D metabolites are bound to specific plasma proteins. Poor absorption may occur in persistent diarrhoea, steatorrhoea and biliary obstruction and therefore the dosage may need to be

increased in these conditions. It is advisable to monitor serum-calcium concentrations during treatment with Vitamin D.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Active ingredient Ergocalciferol preparation containing:

Butylated Hydroxytoluene

Sucrose

Gelatin

Triglycerides, Medium Chain

Modified Maize Starch

Sodium Aluminium Silicate

Other tablet ingredients:

Lactose

Maize Starch

Talc

Magnesium Stearate

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

The product may be packed in the following containers:

1. Opaque plastic containers composed of polypropylene tubes and polyethylene tamper evident closures in pack sizes of 28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1000 tablets.

2. Opaque plastic containers composed of either high density polypropylene or high density polyethylene with a tamper-evident or child-resistant tamper-evident closure composed of high density polyethylene with a packing inclusion of standard polyether foam or polyethylene or polypropylene filler in pack sizes of 28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1000 tablets.

3. Blister packs of aluminium/opaque PVC in pack sizes of 28, 30, 56, 60, 84, 90 and 112 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No specific instructions for use/handling

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
Key House
Sarum Hill
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RG21 8SR
UK

8. MARKETING AUTHORISATION NUMBER

PL 20416 / 0033

9 Date of the first authorisation or renewal

08/09/2005

10 DATE OF REVISION OF THE TEXT

13/10/2023