SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Colecalciferol 800 IU Soft Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

800IU Colecalciferol (equivalent to 20 micrograms vitamin D3)

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Capsule, soft (Capsule)

Blue translucent Capsule

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The prevention and treatment of vitamin D deficiency.

As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Colecalciferol is indicated in adults, the elderly and adolescents.

4.2 Posology and method of administration

Posology

Vitamin D deficiency in adults and the elderly (serum levels <25 nmol/l (<10 ng/ml))

1-4 capsules (800-3200 IU) daily for up to 12 weeks dependent upon the severity of the disease and the patient's response to treatment.

Vitamin D insufficiency in adults and the elderly (serum levels 25 – 50 nmol/l (10-20 ng/mL))

AND

long term maintenance therapy following treatment of deficiency in adults and the elderly

AND

Prevention of vitamin D deficiency

1-2 Capsules (800-1600 IU) daily

Vitamin D deficiency or insufficiency in children over 12 years – 1 capsule daily depending on the severity of the disease and the patient's response to treatment. Should only be given under medical supervision.

As an adjunct to specific therapy for osteoporosis

1 capsule daily

<u>During pregnancy and breast-feeding</u>

Treatment of vitamin D deficiency

1 – 5 capsules (800 – 4000 IU) daily.

Long term maintenance therapy following treatment of deficiency

1 – 2 capsules (800 – 1600 IU) daily.

Colecalciferol should not be used in children under 12 years.

Method of administration

Oral

The capsules should be swallowed whole (not chewed) with water.

4.3 Contraindications

Hypersensitivity to vitamin D or any of the excipients in the product

Hypervitaminosis D

Nephrolithiasis

Diseases or conditions resulting in hypercalcaemia and/or hypercalciuria

Severe renal impairment

4.4 Special warnings and precautions for use

Vitamin D should be used with caution in patients with impairment of renal function 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 insufficiency, vitamin D in the form of colecalciferol is not metabolised normally and other forms of vitamin D should be used (see section 4.3, contraindications).

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

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

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

The need for additional calcium supplementation should be considered for individual patients. Calcium supplements should be given under close medical supervision.

Medical supervision is required whilst on treatment to prevent hypercalcaemia.

During long-term treatment with a daily dose exceeding 1,000 IU vitamin D the serum calcium values must be monitored.

Colecalciferol should not be given to children.

4.5 Interaction with other medicinal products and other forms of interaction

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.

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

The cytotoxic agent actinomycin and imidazole antifungal agents interfere with vitamin D activity by inhibiting the conversion of 25-hydroxyvitamin D to 1,25-dihydroxyvitamin D by the kidney enzyme, 25-hydroxyvitamin D-1-hydroxylase.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of colecalciferol in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The recommended daily intake for pregnant women is 400 IU, however, in women who are considered to be vitamin D deficient a higher dose may be required. During pregnancy women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment.

Vitamin D and its metabolites are excreted in breast milk. Overdose in infants induced by nursing mothers has not been observed, however, when prescribing additional vitamin D to a breast-fed child the practitioner should consider the dose of any additional vitamin D given to the mother.

4.7 Effects on ability to drive and use machines

Colecalciferol has no influence on the 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, <1/100) or rare (>1/10,000, <1/1,000).

Metabolism and nutrition disorders

Uncommon: Hypercalcaemia and hypercalciuria.

Skin and subcutaneous disorders

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 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

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 vitamin D and rehydration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin D and analogues

ATC code: A11CC05

In its biologically active form vitamin D_3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of vitamin D_3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D_3.

5.2 Pharmacokinetic properties

The pharmacokinetics of vitamin D is 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

Vitamin D is well known and is a widely used material and has been used in clinical practice for many years. As such toxicity is only likely to occur in chronic overdosage where hypercalcaemia could result.

Colecalciferol has been shown to be teratogenic in high doses in animals (4-15 times the human dose). Offspring from pregnant rabbits treated with high doses of vitamin D had lesions anatomically similar to those of supravalvular aortic stenosis and offspring not showing such changes show vasculotoxicity similar to that of adults following acute vitamin D toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content

Maize Oil, refined

Butylated hydroxytoluene (BHT) (E321)

Capsule shell

Glycerol (E422) Purified Water

Brilliant Blue W.S (E133)

Gelatin (E441)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

Store blister foil in original container in order to protect from light.

6.5 Nature and contents of container

Opaque, white PVC/PVdC blister tray with aluminium foil.

Pack sizes: 28, 30, 56, 60, 90.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Internis Pharmaceuticals Ltd. (trading as 'STADA')

Linthwaite Laboratories

Linthwaite

Huddersfield

West Yorkshire

HD7 5QH

UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 40861/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/07/2025

10 DATE OF REVISION OF THE TEXT

17/07/2025