SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

STRIVIT-D3 800 IU Capsules, Soft

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 800IU Colecalciferol (equivalent to 20 micrograms vitamin D_3)

Excipients
Maize oil, refined:

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule, soft (Capsule)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For 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
For 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.

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

As an adjunct to specific therapy for osteoporosis, 1 capsule 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.

Dosage in hepatic impairment
No Dose adjustment is required

Dosage in renal impairment
Colecalciferol should not be used in patients with severe renal impairment (see section 4.3).

Paediatric population
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
- Nephrocalcinosis
- 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).

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 hypercalciuria (exceeding 300 mg (7.5 mmol)/24 hours) or signs of impaired renal function the dose should be reduced or the treatment discontinued.

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.

Paediatric population
Colecalciferol should not be given to children.

4.5 Interaction with other medicinal products and other forms of interaction

Thiazide diuretics reduce the urinary excretion of calcium. Due to the increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

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

Pregnancy
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. Colecalciferol can be used up to 2,000 IU/day only in case of a Vitamin D deficiency.

Breast-feeding
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.

Fertility

There are no data on the effect of Colecalciferol on fertility. However, normal endogenous levels of vitamin D are not expected to have any adverse effects on fertility.

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).

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

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 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 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

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. There is no further 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

Capsule Content

Maize oil, refined

Capsule Shell

Gelatin
Glycerol (E 422)
Brilliant Blue Supra containing Brilliant blue for coloring of food (E-133), sodium chloride and sodium sulphate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

Keep the blister in the outer carton in order to protect from light

6.5 Nature and contents of container

Coated PVC film with aluminum blister foil packed in cartons

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

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

Strides Pharma UK Ltd.
Unit 4, Metro Centre, Tolpits Lane,
Watford, Hertfordshire WD 189SS,
United Kingdom

8. MARKETING AUTHORISATION NUMBER(s)

PL 13606/0226

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/01/2016

10. DATE OF REVISION OF THE TEXT

04/12/2018