

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

STRIVIT-D3 3,200 IU Capsules, Soft

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 3,200 IU Colecalciferol (equivalent to 80 micrograms vitamin D₃)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsule, soft (Capsule)

Green to greenish yellow coloured translucent oval shaped soft gelatin capsules containing clear yellow oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of vitamin D deficiency (serum 25(OH)D <25 nmol/l).

STRIVIT-D3 is indicated in adults and the elderly.

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 capsule (3,200 IU) daily for up to 12 weeks dependent upon the severity of the disease and the patient's response to treatment.

Not all given recommended doses can be achieved with this product.

Dosage in hepatic impairment

No dose adjustment is required.

Dosage in renal impairment

In patients with mild or moderate renal impairment, no specific adjustment is required. STRIVIT-D3 should not be used in patients with severe renal impairment (see section 4.3).

Paediatric population

Not recommended for use in children.

Pregnancy and breastfeeding

The recommended intake for pregnant women is 400 IU per day or 3200 IU (1 capsule) per week. 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.

STRIVIT-D3 and its metabolites are excreted in breast milk. Overdose in infants induced by nursing mothers has not been observed but allowance for any maternal dose should be made when prescribing vitamin D products to a breast-fed child.

STRIVIT-D3 can be used up to 2,000 IU/day only in case of vitamin D deficiency (maximum 1 capsule every other day).

Method of administration

Oral

The capsules should be swallowed whole (not chewed) with water and may be taken independently from meal.

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

In the case of therapeutic treatment the dose should be established on an individual basis for the patients by regular checking (initially weekly, then once every 2-4 weeks) of plasma calcium levels. During long-term treatment, serum calcium level, urinary calcium excretion and renal function should be monitored by measuring the serum creatinine level. 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.

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).

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

STRIVIT-D3 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.

STRIVIT-D3 3,200 IU Capsules 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 bile-acid binding resins (i.e. cholestyramine, colestipol), orlistat 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 STRIVIT-D3 in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The recommended intake for pregnant women is 400 IU per day or 3200 IU (1 capsule)

per week, however, in women who are considered to be vitamin D deficient a higher dose may be required. STRIVIT-D3 can be used up to 2,000 IU/day only in case of a Vitamin D deficiency (maximum 1 capsule every other day).

Breastfeeding

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 STRIVIT-D3 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

STRIVIT-D3 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

Website: 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 D₃ 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 D₃. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D₃.

5.2 Pharmacokinetic properties

The pharmacokinetics of vitamin D is well known.

Absorption

Vitamin D is well absorbed from the gastro-intestinal tract in the presence of bile.

Distribution and biotransformation

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).

Elimination

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). There is no further information of relevance to the safety assessment in addition to what is stated in other parts of the SPC. 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

Capsule Shell

Gelatin

Glycerol (E 422)

Chlorophyllin copper complex sodium (E141)

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: 7, 10, 14, 20, 28, 30, 56, 60, 84 and 90 capsules.

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

Strides Pharma UK Ltd.

Unit 4, Metro Centre, Tolpits Lane,

Watford, Hertfordshire WD 189SS,

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL13606/0242

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

15/02/2019

10 DATE OF REVISION OF THE TEXT

15/04/2019