SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

STRIVIT-D3 20,000 IU Capsules, Soft

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 20,000 IU Colecalciferol (equivalent to 500 micrograms vitamin D3)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsule, soft (Capsule)

Clear colourless to pale yellow coloured translucent oval shaped soft gelatin capsules containing clear colourless to pale yellow coloured oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of vitamin D deficiency in adults and adolescents with an identified risk.

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

4.2 Posology and method of administration

Posology

The dosage of vitamin D depends on severity of the disease, as well as patients response to treatment. Based on patients needs, capabilities and preferences daily, weekly or monthly dosing regimens can be offered. Lower dosage forms

(e.g. 400 IU, 500 IU, 800 IU and 1,000 IU) are suitable for daily vitamin D supplementation, while higher dosage forms like 20,000 IU contain amounts for weekly or monthly use, which should be taken into consideration. The dosage and the frequency of administration has to be established individually by a physician.

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

Alternatively, national posology recommendations in prevention and treatment of vitamin D deficiency can be followed.

Adults

Prevention of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis:

Recommended dose range is 600 IU- 800 IU per day or equivalent weekly or monthly dose [20,000 IU (1 capsule) per month].

Treatment of vitamin D deficiency:

800 IU per day or equivalent weekly or monthly dose [maximum cumulative dose 20,000 IU (1 capsule) per month]. Higher doses should be adjusted dependent upon desirable serum levels of 25-hydroxycolecalciferol (25(OH)D), the severity of the disease and the patient´s response to treatment.

The dose should not exceed 4,000 IU per day or equivalent weekly [20,000 IU (1 capsule) per week] or monthly dose.

Adolescents:

The dose for adolescents aged 12 years or more should be adjusted dependent upon desirable serum levels of 25-hydroxycolecalciferol (25(OH)D), the severity of the disease and the patient´s response to treatment.

The daily dose should not exceed 4,000 IU per day or equivalent weekly [20,000 IU (1 capsule) per week] or monthly dose.

Paediatric population

STRIVIT-D3 20,000 IU capsules should not be given to children under 12 years of age due to the risk of choking. Instead, it is advisable to use drops or dissolvable tablets.

Hepatic impairment

No dose adjustment is required.

Renal impairment

Patients with mild or moderate renal impairment: no specific adjustment is required. STRIVIT-D3 must not be used in patients with severe renal impairment.

Pregnancy

The recommended daily intake for pregnant women is 400 IU , however, in women who are considered to be vitamin D3 deficient a higher dose may be required [up to 2,000 IU/day or equivalent weekly or monthly dose (60,000 IU (3 capsules) per month)].

Other conditions

In obese patients, patients with malabsorption syndromes, and patients on medications affecting vitamin D3 metabolism, higher doses are required for the treatment and prevention of vitamin D3 deficiency.

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 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 (see section 4.5) . 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, contraindications).

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.

Paediatric population

STRIVIT-D3 20,000 IU Capsules should not be given to children under 12 years.

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 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. STRIVIT-D3 can be used up to 2,000 IU/day only in case of a Vitamin D deficiency.

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)

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:

For UK: 7, 10, 14, 15, 20, 28, and 30 capsules.

For NL: 3, 4, 5 and 6 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 Arcolab International Ltd.

Unit 4, Metro Centre, Tolpits Lane,

Watford, Hertfordshire WD 189SS,

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 28176/0189

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/02/2019

10 DATE OF REVISION OF THE TEXT

15/02/2019