SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Colecalciferol 2000 IU film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains colecalciferol (vitamin D_3) 2000 IU (equivalent to 50 microgram vitamin D_3).

Excipients with known effect
Each film-coated tablet contains 141 mg lactose (as lactose monohydrate) and 4 mg sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Colecalciferol 2000 IU are yellow coloured, round, 9 mm diameter biconvex film-coated tablets, embossed 'S' on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of vitamin D deficiency (serum 25(OH)D < 25 nmol/L) in adults.

4.2 Posology and method of administration

The dosage must be determined individually by the treating doctor, depending on the extent of the necessary vitamin D_3 supplementation.

Posology

One or two tablets per day (equivalent to 2000-4000 IU/day).

After the first month, a lower maintenance dose should be considered dependent upon desirable serum levels of 25-hydroxycholecalciferol (25(OH)D), the severity of the disease and the patient´s response to treatment.

Paediatric population

Colecalciferol should not be used in children and adolescents up to 18 years.

Dosage in hepatic impairment

No dose adjustment is required.

Dosage in renal impairment

In severe renal impairment the dosage must be determined individually by the treating physician dependent upon desirable serum levels of 25-hydroxycholecalciferol (25(OH)D), the severity of the disease and the patient´s response to treatment (see section 4.4).

Method of administration

The tablets can be swallowed whole. The tablets can be taken with food.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Diseases and/or conditions resulting in hypercalcaemia or hypercalciuria
- Nephrolithiasis
- Nephrocalcinosis
- Hypervitaminosis D

4.4 Special warnings and precautions for use

Monitoring

During treatment, serum and urinary 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.

Sarcoidosis

Vitamin D_3 should be prescribed with caution to patients suffering from sarcoidosis due to risk of increased metabolism of vitamin D into its active form. These patients should be monitored with regard to the calcium content in serum and urine.

Renal impairment

Vitamin D_3 should be used with caution in patients with renal impairment 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 impairment, vitamin D in the form of cholecalciferol is not metabolised normally (see section 4.2).

Pseudohypoparathyroidism

Cholecalciferol is not recommended if pseudohypoparathyroidism is present (the need for vitamin D may be reduced by the sometimes normal sensitivity to vitamin D_3,

with a risk of long-term overdose). In such cases, more manageable vitamin D_3 derivates are available.

Other vitamin D_3 containing products

The content of vitamin D (2000 IU) in this medicinal product should be considered when prescribing other medicinal products containing vitamin D. Additional doses of vitamin D should be taken under close medical supervision.

Excipients

This medicinal product contains lactose and sucrose.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption and patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Thiazide diuretics

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.

Phenytoin and barbiturates

Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D since the metabolism increases.

Digitalis

Excessive dosing of vitamin D can induce hypercalcaemia, which may increase the risk of digitalis toxicity and serious arrhythmias due to the additive inotropic effects. The electrocardiogram (ECG) and serum calcium levels of patients should be closely monitored.

Glucocorticoids

Glucocorticoid steroids may increase vitamin D metabolism and elimination. During concomitant use, it may be necessary to increase the dose of Colecalciferol tablets.

Ion exchange resins and laxatives

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

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data from the use of cholecalciferol in pregnant women. Vitamin D deficiency is harmful for mother and child. High doses of vitamin D have been shown to have teratogenic effects in animal experiments (see section 5.3).

Overdose of vitamin D must be avoided during pregnancy, as prolonged hypercalcaemia may lead to physical and mental retardation, supravalvular aortic stenosis and retinopathy of the child.

To treat a vitamin D deficiency, the recommended dose is dependent on national guidelines, however, the maximum recommended dose during pregnancy of 4,000 IU/day vitamin D_3 should not be exceeded. Colecalciferol should not be used by pregant women without a vitamin D deficiency.

Breastfeeding

Vitamin D_3 and its metabolites are excreted in breast milk. No adverse events have been observed in infants. Colecalciferol can be used at recommended doses during lactation in case of a vitamin D deficiency. This should be considered when giving additional vitamin D to the child.

Fertility

There are no data on the effect of cholecalciferol 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 or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions frequencies are defined as:

uncommon (≥1/1,000, <1/100),

rare (≥1/10,000, <1/1,000)

not known (cannot be estimated from the available data).

Gastrointestinal disorders

Not known: constipation, flatulence, nausea, abdominal pain, diarrhea

Immune system disorders

Not known: Hypersensitivity reactions such as angioedema or laryngeal oedema.

Metabolism and nutrition disorders

Uncommon: Hypercalcaemia and hypercalciuria.

Skin and subcutaneous disorders

Rare: Pruritus, rash and urticaria.

Hypercalcaemia

Depending on the dose and duration of treatment, severe and prolonged hypercalcemia with its acute (cardiac arrhythmias, nausea, vomiting, psychic symptoms, disturbances of consciousness) and chronic (increased urgency to urinate, increased thirst, loss of appetite, weight loss, kidney stones, kidney calcification, calcification in tissues outside the skeleton) consequences can occur. A fatal outcome has been reported in very rare cases (see also section 4.4 and 4.9).

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, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose can lead to hypervitaminosis D. An excess of vitamin D causes abnormally high levels of calcium in the blood.

Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, renal calculi and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification.

Treatment of hypercalcaemia: The treatment with vitamin D must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, and cardiac glycosides must also be discontinued. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin D and analogues, cholecalciferol

ATC code: A11C C05

Vitamin D increases the intestinal absorption of calcium and phosphate.

Administration of vitamin D_3 counteracts development of rickets in children and osteomalacia in adults. It also counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which causes increased bone resorption.

In addition to bone and intestinal mucosa many other tissues have vitamin D receptors, to which the active hormonal form of vitamin D, calcitriol, binds.

5.2 Pharmacokinetic properties

Vitamin D

Absorption

Vitamin D is easily absorbed in the small intestine.

Distribution

Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Vitamin D, which is not metabolised, is stored in adipose and muscle tissues.

Metabolism

Cholecalciferol is converted in the liver by hydroxylation to 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1.25-dihydroxycholecalciferol. 1.25-dihydroxycholecalciferol is the active metabolite responsible for increasing calcium absorption.

Elimination

Vitamin D is excreted in faeces and urine.

5.3 Preclinical safety data

At doses far higher than the human therapeutic range teratogenicity has been observed in animal studies. 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

Tablet core:
lactose monohydrate
powdered cellulose (E460 (ii))
modified food starch
maize starch
croscarmellose sodium (E468)
sucrose
colloidal anhydrous silica (E551)
magnesium stearate (E470b)
sodium ascorbate (E301)
medium chain triglycerides
All-rac-alpha-tocopherol (E307)

Coating:
polyvinyl alcohol (E1203)
titanium dioxide (E171)
macrogol 3350
talc (E553b)
quinoline yellow aluminum lake (E104)
yellow iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

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

6.5 Nature and contents of container

Colecalciferol 2000 IU film-coated tablets: 30, 90 and 100 film-coated tablets in opaque PVC/PVdC-Alu blisters and box.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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Dublin 2,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 24837/0172

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/04/2024

10 DATE OF REVISION OF THE TEXT

11/06/2024