Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Colecalciferol EQL Pharma 2000 IU tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Colecalciferol EQL Pharma 2000 IU tablet: Each tablet contains colecalciferol 2000 IU (equivalent to 50 microgram vitamin D_3).
Excipient(s) with known effect
Each tablet contains isomalt 228 mg and sucrose 4 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White to off white, oblong, uncoated tablets plain on both sides, 14 mm long

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Treatment of vitamin D deficiency in adults, elderly and adolescents. Vitamin D deficiency is defined as serum levels of 25-hydroxycolecalciferol (25(OH)D) < 25 nmol/l.

4.2 Posology and method of administration

Posology

The dose should be established on an individual basis depending on the desirable serum levels of 25-hydroxycolecalciferol (25(OH)D), the severity of the disease and the patient´s response to treatment. The dosage has to be established individually by a physician. The tablets cannot be divided for dosing and so the appropriate formulation should be used to achieve the recommended dose which is as follows:

Adults and elderly
Treatment of vitamin D deficiency: 800 – 4000 IU per day.
The daily dose should not exceed 4000 IU (two tablets).
A lower maintenance dose of 800 – 1600 IU/day or weekly or monthly equivalent should be considered one month after loading dose.

Adolescents aged 12 – 18 years:
Treatment of vitamin D deficiency: 800 – 1600 IU/day
The daily dose should not exceed 2000 IU per day. A lower maintenance dose of 800 – 1600 IU/day or weekly or monthly equivalent should be considered one month after loading dose.

The safety and efficacy of colecalciferol in children under 12 years have not been established.

Dosage in hepatic impairment
No dose adjustment is required.

Dosage in renal impairment
Colecalciferol should not be used in patients with severe renal impairment.

Method of administration
The tablets can be swallowed whole or crushed. The tablets can be taken with food.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Colecalciferol 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.

Long-term treatment
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.

Renal impairment
Colecalciferol 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.

Concomitant use of vitamin D
The content of vitamin D in Colecalciferol EQL Pharma should be considered when prescribing other medicinal products containing vitamin D. Additional doses of vitamin D should be taken under close medical supervision. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently.

Sucrose, isomalt and sodium
Colecalciferol EQL Pharma contains sucrose and isomalt. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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

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.

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

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

Treatment with orlistat may reduce the absorption of fat-soluble vitamins, including vitamin D_3.

As vitamin D can increase intestinal absorption and stimulate renal reabsorption of phosphate, concomitant use of products containing high amounts of phosphate such as certain osmotic bowel-emptying preparations may increase the risk of hyperphosphataemia and therefore caution is advised.

4.6 Fertility, pregnancy and lactation

Pregnancy
Overdoses of vitamin D have been shown to have teratogenic effects in animal experiments (see section 5.3). There are no indications that vitamin D at therapeutic doses is teratogenic in humans.
Colecalciferol should be used during pregnancy only in the case of a vitamin D deficiency.
Colecalciferol is not recommended during pregnancy in patients without a vitamin D deficiency.

Breastfeeding
Vitamin D can be used during breast-feeding. Colecalciferol is excreted in human milk. This should be considered when giving additional vitamin D to the child.

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 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 to <1/100), rare (≥1/10,000 to <1/1,000) or not known (cannot be estimated from the available data).

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

Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.

Skin and subcutaneous tissue 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 national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

Overdose can lead to hypervitaminosis D. An excess of vitamin D causes abnormally high levels of calcium in the blood, which can eventually severely damage the soft tissues, and kidneys. Tolerable Upper Intake Level for vitamin D3 (colecalciferol) is set at 4000 IU (100 µg) per day. Vitamin D3 should not be confused with its active metabolites.

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 central venous pressure should be followed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin D and its analogues, 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

Absorption
Vitamin D is easily absorbed in the small intestine.

Distribution
Colecalciferol and its metabolites circulate in the blood bound to a specific globulin. Colecalciferol is converted in the liver by hydroxylation to 25-hydroxycolecalciferol. It is then further converted in the kidneys to 1,25- dihydroxycolecalciferol. 1,25-dihydroxycolecalciferol is the active metabolite responsible for increasing calcium absorption. Vitamin D, which is not metabolised, is stored in adipose and muscle tissues.

Elimination
Vitamin D is excreted in faeces and urine.

5.3 Preclinical safety data

Effects in non-clinical repeat-dose toxicity studies were observed only at exposures considered sufficiently in excess of the maximum human exposure, indicating toxicity is only likely to occur in chronic overdosage where hypercalcaemia could result.

At doses far higher than the human therapeutic range, teratogenicity has been observed in animal studies, offspring from pregnant rabbits treated with high doses of vitamin D had lesions anatomically similar to supravalvular aortic stenosis. 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

All-rac-alpha-tocopherol (E307)
Isomalt (E953)
Magnesium stearate
Modified food (maize) starch
Pregelatinized maize starch
Sodium ascorbate (E301)
Sucrose
Triglycerides, medium chain

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original bottle in order to protect from light and moisture.

6.5 Nature and contents of container

100 in HDPE plastic bottles.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

EQL Pharma AB
Stortorget 1
Lund
222 23
Sweden

8 MARKETING AUTHORISATION NUMBER

PA22981/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th July 2021
Date of last renewal: 13th April 2026

10 DATE OF REVISION OF THE TEXT

August 2025