Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Desunin 800 IU Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains colecalciferol (vitamin D_3) 800 IU (equivalent to 20 microgram vitamin D_3).

Excipients with known effect:
Each tablet contains isomalt 91.0 mg and sucrose 1.68 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
White to light yellow, biconvex, 7 mm in diameter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency preferably in combination with calcium.

4.2 Posology and method of administration

Posology
Recommended dose: One tablet per day.

Higher doses can be necessary in treatment of vitamin D deficiency, where the dose 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 4000 IU (five tablets per day).

Pediatric population
The safety and efficacy of Desunin in children under 12 years have not been established.

Dosage in hepatic impairment
No dose adjustment is required.

Dosage in renal impairment
Desunin should be used with caution in patients with renal impairment (see section 4.4).

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

Desunin 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.

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.

Desunin 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 may therefore be needed.

The content of vitamin D (800 IU) in Desunin 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.

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

This medicinal product 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 Desunin tablets.

Simultaneous treatment with orlistat or 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

Fertility

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

Pregnancy

Desunin should be used during pregnancy, only in the case of a vitamin D deficiency. Desunin is not recommended during pregnancy in patients without a vitamin D deficiency as the daily intake should not exceed 600 IU vitamin D.
Studies in animals have shown reproductive toxicity of high doses of vitamin D (see section 5.3).
There are no indications that vitamin D at therapeutic doses is teratogenic in humans.

Breast-feeding

Vitamin-D can be used during breast-feeding. Vitamin D3 passes into breast milk. This should be considered when giving additional vitamin D to the child.

4.7 Effects on ability to drive and use machines

There are no data about the effect of this product on driving capacity. An effect is, however, unlikely.

4.8 Undesirable effects

Adverse reactions frequencies are defined as: uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <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 angioedema 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 HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

Overdose can lead to hyper-vitaminosis 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 CVP should be followed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin supplements
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 and metabolism:
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

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

Pregelatinized maize starch
Isomalt (E 953)
Magnesium stearate
Sucrose
Sodium ascorbate
Triglycerides, medium chain
Silica, colloidal anhydrous
Modified food (maize) starch
All-rac-alpha-tocopherol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30^{o}C.
Store the tablets in the original container, in order to protect from light. Keep the container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

30, 60, 90 in white opaque PVC/PVDC/aluminium blister in outer paper carton.
250 tablets in plastic containers of HDPE with LDPE snap on cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Viatris Healthcare Limited
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8 MARKETING AUTHORISATION NUMBER

PA23355/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th June 2012

Date of last renewal: 18th April 2017

10 DATE OF REVISION OF THE TEXT

June 2023