AUSTRALIAN PRODUCT INFORMATION – OSTELIN SPECIALIST RANGE VITAMIN D 7000IU (COLECALCIFEROL) SOFT CAPSULE

1 NAME OF THE MEDICINE

Colecalciferol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Ostelin Specialist Range Vitamin D 7000IU capsule contains 175mcg of colecalciferol.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Colecalciferol is a naturally occurring form of Vitamin D. It is produced from 7-dehydro cholesterol, a sterol present in mammalian skin, by ultraviolet irradiation. Colecalciferol appears as white/almost white crystals.

Ostelin Specialist Range Vitamin D are formulated as soft capsules for oral administration.

Ostelin Specialist Range Vitamin D 7000IU are blue coloured capsules.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For:

The treatment of vitamin D deficiency in adults and adolescents as directed by your medical practitioner or pharmacist.

The prevention of vitamin D deficiency in high risk individuals under the supervision of a medical practitioner or pharmacist.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults and adolescents from 12 years of age.

Swallow the capsule with a glass of water.

Recommended doses:

Ostelin Specialist Range Vitamin D 7000IU: one capsule to be taken weekly.

Take the capsule on the same day each week.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substances or to any of the excipients.

Colecalciferol should not be given to patients with hypercalcaemia (see Section 4.8 Adverse Effects (undesirable Effects) and 4.9 Overdose).

Diseases and/or conditions, which lead to hypercalcaemia (e.g. nephrocalcinosis, myeloma, bone metastases, primary hyperparathyroidism, sarcoidosis, prolonged immobilisation accompanied by hypercalcaemia).

Hypervitaminosis D.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The content of Ostelin Specialist Range Vitamin D 7000IU should be considered when prescribing other medicinal products containing vitamin D and preparation containing calcium. Prescription of Ostelin Specialist Range Vitamin D 7000IU with other vitamin D supplements should be done under close medical supervision.

Recommended Monitoring

The monitoring of urinary and serum calcium, vitamin D and parathyroid hormone levels while taking colecalciferol is recommended to assess the response to treatment.

Unregulated overproduction of calcitrol

Vitamin D3 may increase the magnitude of hypercalcemia and/or hypercalcuria when administered to patients with diseases associated with unregulated overproduction of calcitriol (e.g., leukaemia, lymphoma, sarcoidosis).

Impaired renal function, renal calculi or heart disease

Colecalciferol should be given with care to patients with renal failure, kidney stones, impaired renal function or calculi or heart disease who might be at increased risk of organ damage if hypercalcaemia occurred. Chronic hypercalcaemia can result in calcium deposits in many tissues, such as the arteries, kidneys and other soft tissue which may lead to hypertension and renal failure. Plasma phosphate concentrations should be controlled in these patients during vitamin D therapy to reduce the risk of ectopic calcification.

Use in the elderly

Studies have shown that the elderly may have an increased need for vitamin D due to a possible decrease in the capacity of the skin to produce pre-vitamin D3, or a decrease in exposure to the sun or impaired renal function or impaired vitamin D absorption.

Paediatric use

Ostelin Specialist Range Vitamin D 7000IU is not recommended in children less than 12 years old.

Effects on laboratory tests

The effect of colecalciferol on laboratory tests has not been studied.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

There is an increased risk of hypercalcaemia if colecalciferol is given with thiazide diuretics. Thiazide diuretics reduce the urinary excretion of calcium. Serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

There is an increased risk of hypercalcaemia if colecalciferol is given with calcium and phosphate. Calcium concentrations should be monitored in those situations.

Some anti-epileptics may increase colecalciferol requirements (e.g. carbamazepine, phenobarbital, phenytoin and primidone).

Isoniazid may reduce the effectiveness of colecalciferol.

Concomitant treatment with rifampicin, phenytoin or barbiturates can decrease the effect of vitamin D3 because of metabolic activation.

Corticosteroids may counteract the effect of colecalciferol. Systemic corticosteroids reduce calcium absorption. Moreover the effect of vitamin D may be decreased.

The absorption and therefore the efficacy of ketoconazole will be decreased by the concomitant intake with Ostelin Specialist Range Vitamin D 7000IU.

Some medicines may impair the absorption of Vitamin D (including orlistat, bile acid sequestrants such as colestipol, antacids, calcium and phosphate supplements).

Simultaneous treatment with ion exchange resins such as cholestyramine may reduce the gastrointestinal absorption of vitamin D. Therefore a time interval as long as possible between the intakes is recommended.

Concomitant use of Vitamin D with Vitamin D analogues, is not recommended due to the additive effect and increased toxic potential.

Healthcare professionals should advise patients in relation to any sort of interaction.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data are available regarding the use of colecalciferol and fertility.

Use in pregnancy

Colecalciferol is exempt from pregnancy classification by TGA. No data is available for colecalciferol. However hypercalcaemia during pregnancy may produce congenital disorders in the offspring, and neonatal hypoparathyroidism. However the risks to the foetus of untreated maternal hypoparathyroidism are considered greater than the risks of hypercalcaemia due to vitamin D therapy.

Use in lactation

Vitamin D is distributed into breast milk, and its concentration appears to correlate with vitamin D levels in the serum of exclusively breast-fed infants. The American Academy of Paediatrics considers the use of vitamin D to be usually compatible with breast feeding, although it is recommended that the infant be closely monitored for hypercalcaemia or clinical manifestations of vitamin D toxicity if the mother is receiving pharmacological doses of vitamin D.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

There are no data available on the effect on ability to drive and use machines.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Supplementation with Vitamin D has a long established history of safe use. Excessive intake of colecalciferol over extended periods of time can lead to the development of hyperphosphataemia or hypercalcaemia (see Section 4.9 Overdose).

Metabolism and nutrition disorders:
Not known: Hypercalcaemia. Hypercalciuria.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Overdose can lead to hypervitaminosis and hypercalcaemia (symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, renal function can be impaired early stage (polyuria, polydipsia, nocturia), chronic overdose with resulting hypercalcaemia can cause vascular and soft tissue calcification).

In hypervitaminosis D cases of weakness, fatigue, muscle pain, polydipsia, polyuria, decreased appetite have been reported.

In the case of an intoxication, treatment should be stopped immediately and the fluid deficiency should be compensated.

Excessive intake of colecalciferol leads to the development of hypercalcaemia and its associated effects including hypercalciuria, hyperphosphataemia, ectopic calcification and renal and cardiovascular damage.

Other symptoms of overdose include lassitude, bone pain, weight loss, diarrhoea, sweating, headache, somnolence, apathy, proteinuria, depression, vague aches, stiffness, anaemia, hypertension, cardiac arrhythmias, urinary tract infections and vertigo.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Vitamin D compounds are fat soluble sterols which are essential for the absorption and utilisation of calcium and phosphorus (in the form of inorganic phosphate) in the body to maintain normal calcification of the skeleton and bone mineralisation.

Vitamin D maintains the blood calcium at supersaturating levels such that it is deposited in the bone as calcium hydroxyapatite. When dietary calcium is inadequate for the body's needs, 1,25-dihydroxyVitamin D [1,25(OH)2D or calcitriol], the active form of Vitamin D, together with parathyroid hormone, can mobilise stem cells in bone marrow to become mature osteoclasts which in turn increase the mobilisation of calcium stores from bone.

Vitamin D plays an essential role in bone health. Colecalciferol (also known as Vitamin D3) is used for the prevention and treatment of Vitamin D deficiency. Colecalciferol helps to prevent the problems usually associated with Vitamin D deficiency such as osteoporosis, muscle weakness, increased risk of bone fractures. Vitamin D plays an essential role in calcium metabolism, bone growth and mineralisation. By improving the absorption of bone-building calcium from the intestine, Vitamin D is important to the growth and maintenance of a strong skeleton. Vitamin D also helps to control calcium levels in the blood and helps to maintain muscle strength. Vitamin D is also thought to play a role in maintaining the immune system.

In infants and unborn babies, Vitamin D deficiency may result in slow growth and rickets (bone weakness), and may increase the risk of fractures and falls in the elderly. Patients at risk of Vitamin D deficiency include those that are house bound, dark-skinned and those who lack exposure to sunlight.

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Vitamin D is readily absorbed from the small intestine. Bile is essential for adequate absorption. It is stored mainly in the liver and Vitamin D is also found in fat, muscle, skin and bones. The primary route of Vitamin D excretion is in the bile; only a small percentage is found in the urine.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

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5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data are available regarding the use of colecalciferol and genotoxicity.

Carcinogenicity

No data are available regarding the use of colecalciferol and carcinogenicity.

Overdoses of vitamin D have been associated with teratogenic effects in animal studies.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

dl-alpha-tocopherol, soya oil, gelatin, allura red AC, patent blue V, glycerol, purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Ostelin Specialist Range Vitamin D capsules are packaged in a PVC/PE/PVDC/aluminum blister foil contained in a carton.

Ostelin Specialist Range Vitamin D 7000IU supplied in a pack size of 24, 48 and 4* (sample pack).

*note that the sample pack is not for sale.

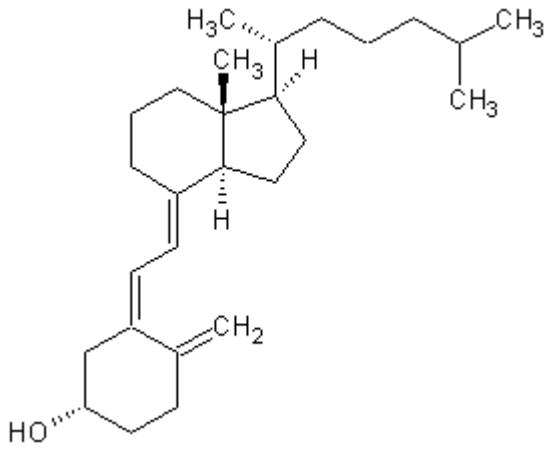
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

The chemical structure of colecalciferol is:



Molecular Formula: $C_{27}H_{44}O$

Molecular Weight =384.6

Chemical Name: *(5Z,7E)*-9, 10-Secocholesta-5,7,10(19)-trien-3β-ol

CAS number

67-97-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 3 (Pharmacist Only Medicine)

8 SPONSOR

Sanofi- Aventis Healthcare Pty Ltd T/A Sanofi Consumer Healthcare
87 Yarraman Place
Virginia, Queensland, 4014
Australia

9 DATE OF FIRST APPROVAL

7th September 2016

10 DATE OF REVISION

18th April 2024

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
3	Removed printed with '7000'
6	Removed 'opacode WB water based monogramming ink NSP-78-18022 white'