D-VOTAL
(Cholecalciferol)

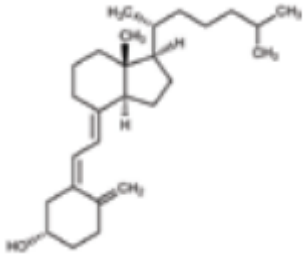
Injection

For Oral / I.M Administration

COMPOSITION / DESCRIPTION:

Each ml contains:
Cholecalciferol (Vitamin D3) 5mg
(Product Complies U.S.P. Specifications)

Vitamin D3 (Cholecalciferol) is a fat soluble vitamin and is a precursor of the active hormone 1, 25-dihydroxy Cholecalciferol, also known as calcitriol. It is derived from 7-dehydrocholesterol. Vitamin D3 is the only vitamin the body can manufacture from sunlight (UVB). It is a secosteroid, that is, a steroid molecule with one ring open and IUPAC name is (3β,5Z,7E)-9,10-secocholesta5,7,10(19)-trien-3-ol. The chemical formula of Cholecalciferol is C27H44O



THERAPEUTIC INDICATIONS

It is indicated in prophylaxis and/or treatment of deficiency in Vitamin D3.

DOSAGE AND ADMINISTRATION

The ampoule of Vitamin D3 Cholecalciferol can be administered through
- Oral route or
- IM Route

Infants receiving milk enriched with Vitamin D:

0.5ml or ½ ampoule (100000 IU) every 6 months.

Infants breastfeeding and up to 5 years of age and do not receive milk enriched with

vitamin D:

1ml or 1 ampoule (200000 IU) every 6 months.

Adolescents:

1ml or 1 ampoule (200000 IU) every 6 months (in winter).

Pregnant women:

0.5ml or ½ ampoules (100000 IU) at the sixth or seventh month of pregnancy, repeated once at

the end of a month if the final trimester starts up in winter or in case of non-solar exposure.

Elderly:

0.5ml or ½ ampoule (100000 IU) every 3 months.

In case of digestive disorders:

0.5ml-1ml or ½ - 1 ampoule (100000 - 200000 IU) every 3 months.

In patients receiving anticonvulsant treatment:

0.5ml-1ml or ½ to 1 ampoule (100000 - 200000 IU) every 3 months.

Deficiency in vitamin D (rickets, osteomalacia, hypocalcaemia) in new born:

1ml or 1 ampoule (200000 IU) repeated after 1 to 6 months

CONTRAINDICATIONS

It is contraindicated in:
Hypercalcemia, hypercalciuria, calcic lithiasis.
Hypersensitivity to any of the components of the product.
Kidney insufficiency or renal impairment.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

-Treatment with Vitamin D3 (Cholecalciferol) must be discontinued, if hypercalcemia and hypercalciuria occur.
-To avoid any Overdosage, total doses of Vitamin D must be taken in consideration in case of association of other drugs containing this vitamin.
-In malabsorption
-Avoid using vitamins, mineral supplement and antacid unless prescribed by the physician.
-Caution must be taken if patient
-Had an allergic reaction to vitamin D.
-Has a high level of blood calcium or vitamin D

DIRECTIONS FOR USE:

1.

- ایمپول پر دیئے گئے سفید نشان کو اس پر چڑھے ہوئے خول کی لال لمبی سطر سے ملائیں۔

- Coincide the white mark of the ampoule with red straight line on the sleeve.

2.

- لال لمبی سطر کی مخالف سمت میں انگوٹھے کا ہلکا سا زور دے کر توڑیں۔ اس طریقے سے ایمپول باحفاظت آسانی سے ٹوٹ جائی گا۔

- Break the ampoule by pushing with slight thumb pressure against the red straight line. By this method ampoule will be broken safely and easily.

DRUG INTERACTIONS

There is increased risk of hypercalcemia, if Cholecalciferol is given with thiazide diuretics, calcium or phosphate.
Cholecalciferol requirements may increase while using anti-epileptics e.g. carbamazepine, phenobarbitone, phenytoin, pirimidone. Rifampicin and isoniazid may reduce the efficacy of Cholecalciferol.
Cholecalciferol effect may be counteracted by the use of corticosteroids, digoxin or any cardiac glycoside.
Absorption of Cholecalciferol may be reduced when taken with cholestyramine, colestipol, mineral oil, orlistat and ketoconazole.

FERTILITY, PREGNANCY AND LACTATION

Cholecalciferol can be prescribed during pregnancy and to nursing mothers if necessary, when used in daily recommended amounts below 200,000 IU.

ADVERSE DRUG REACTION

Hyperphosphatemia or hypercalcaemia (in excessive intake) and associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, renal and Cardio Vascular damage

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 pv@searlecompany.com

OVERDOSE

In the event of an overdose the following symptoms may occur which includes headache, fatigue, weight loss, growth retardation, anorexia, drowsiness, dry skin, itchy skin, nausea, vomiting, constipation, muscle or bone pain, metallic taste in the mouth, hypercalcemia, hypercalciuria, Hyperphosphatemia, hyperphosphaturia, intense thirst, polyuria, arterial hypertension, dehydration and severe pain in upper stomach spreading to back or fainting

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Calcitriol which is the metabolite of Cholecalciferol exerts its effect by binding to vitamin D receptors (VDRs) which are widely distributed through many body tissues. Cholecalciferol also has anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant and mood-modulatory activities

and along with parathyroid hormone and calcitonin it regulates serum calcium concentration.

Pharmacokinetic properties

Absorption:
Cholecalciferol is well absorbed from small intestine. Presence of bile is essential for adequate intestinal absorption. Absorption is reduced in liver or biliary disease.

Distribution:
Cholecalciferol is bound to a specific α-globulin and albumin in plasma. It can be stored in adipose and muscle tissue for longer period of time and it may distribute into breast milk.

Metabolism:
Cholecalciferol is hydroxylated in liver by the enzyme Vitamin D 25-hydroxylase to form 25- hydroxycholecalciferol calcifediol. Calcifediol is then hydroxylate the kidneys by the enzyme vitamin D1-Hydroxylase to form the active metabolites 1, 25-dihydroxycholecalciferol (calcitriol). Calcitriol is further metabolised in the kidneys, including the formation of the 1, 24, 25-trihydroxy derivatives.

Excretion:
Cholecalciferol is excreted mainly in the bile and feces with only small amounts appearing in urine. Elimination half-life of calcitriol is 5 to 8 hours. Pharmacological activities persist for 3 to 5 days

PRESENTATION

D-Votal 5mg/ml Injection is available in pack of 1's.

STORAGE INSTRUCTIONS

- Keep all medicines out of reach of children.
- To be sold on prescription of a registered medical practitioner only.
- Do not freeze.
- Keep in cool and dry place, protect from light.
- Store below 25°C.
- Do not use if solution is cloudy or it contains un-dissolved particle(s).

REGISTRATION NUMBER

Mfg. Lic. No.: 000586
Reg. No.: 077571

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION – As per registrations letter

Searle IV Solutions (Pvt.) Limited.
1.5 Km - Manga Raiwind Road, Manga Mandi,
Distt. Lahore - Pakistan.
PIL code: 112017
Rev Code: 000000

DATE OF PUBLICATION OF THE PACKAGE INSERT

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