

# VITA D Inj. I.M.

(Cholecalciferol)

Prescription Drug  
Classification No.: 03110

## Composition. 1 mL contains:

- Active ingredient: Cholecalciferol (EP) (as cholecalciferol) ..... 5 mg
- Other ingredients: Medium-chain triglycerides, dl- $\alpha$ -tocopherol

## Description

Clear pale yellow transparent oily solution contained in a brown glass ampoule for injection.

## Indications / Efficacy

Prevention and treatment of Vitamin D deficiency in adults and adolescents at risk of Vitamin D deficiency  
Treatment of Vitamin D deficiency in adults with confirmed Vitamin D deficiency

## Dosage and Administration

Use according to physician's prescription. Adjust dosage after confirming serum 25-hydroxyvitamin D concentration.

After administration of this product, treatment effect and tolerability should be evaluated within 3 months in adults and within 6 months in adolescents, and based on this evaluation, the need for re-administration should be determined.

Avoid excessive administration because adverse reactions may increase depending on overdose.

- Adults: Intramuscular injection equivalent to cholecalciferol 200,000 IU
- Adolescents: Intramuscular injection equivalent to cholecalciferol 200,000 IU
- Elderly: Intramuscular injection equivalent to cholecalciferol 100,000 IU
- Total annual dose should not exceed cholecalciferol 600,000 IU.

## Precautions for Use

### 1. Warnings

- 1) To prevent overdose, avoid concomitant administration with Vitamin D-containing medicinal products or Vitamin D-fortified foods.
- 2) Monitor serum calcium concentration. Discontinue administration if serum calcium exceeds 10.5 mg/dL or urinary calcium exceeds 4 mg/kg/day.
- 3) When calcium intake is high, monitor serum calcium concentration and urinary calcium concentration regularly.

## **2. Contraindications**

- 1) Patients with hypersensitivity to any component of this product
- 2) Patients with hypercalcemia or hypercalciuria
- 3) Patients with calcium-containing renal calculi
- 4) Patients at risk of renal stone formation
- 5) Patients with renal impairment
- 6) Immobilized patients
- 7) Patients with sarcoidosis
- 8) Patients with pseudohypoparathyroidism
- 9) Pregnant women and breastfeeding women

## **3. Adverse Reactions**

- 1) The following adverse reactions may occur after administration of cholecalciferol:  
Headache, asthenia, fatigue, myalgia, anorexia, weight loss, growth retardation, nausea, vomiting, constipation, diarrhea, polydipsia, polyuria, dehydration, hypertension, calcium stones, calcification of kidney and vascular tissues, renal impairment, hypercalcemia, arrhythmia, psychiatric symptoms, sensory disturbances, arthralgia, muscle weakness, somnolence, azotemia, hypersensitivity reactions, thirst, confusion, flatulence, abdominal pain, metallic taste, dry mouth, rash, pruritus  
Additionally: Hypercalciuria, hypercalcemia, hyperphosphatemia, hyperphosphaturia may occur.
- 2) Clinical Study.  
In a 6-month placebo-controlled clinical study involving 84 adults aged 20–64 years, the reported adverse drug reactions were mainly injection-site reactions, and newly identified adverse drug reactions were as follows:  
Injection-site granuloma, injection-site nodule, injection-site reaction, injection-site urticaria, injection-site infection

## **4. General Precautions**

- 1) In clinical studies involving patients with Vitamin D deficiency, administration of cholecalciferol increased serum 25-hydroxyvitamin D concentration and parathyroid hormone concentration.
- 2) When administering this product to patients whose serum 25-hydroxyvitamin D concentration is below 10 ng/mL, monitor serum 25-hydroxyvitamin D concentration during treatment.
- 3) Measure serum creatinine every 3–6 months. Especially in elderly patients or patients receiving cardiac glycosides or diuretics, monitor serum creatinine regularly.  
If renal function abnormalities occur, reduce dosage appropriately or discontinue administration depending on patient condition.
- 4) In patients with abnormalities in calcium or phosphorus metabolism, monitor serum calcium concentration and urinary calcium concentration.
- 5) In patients receiving benzodiazepine derivatives, monitor serum calcium concentration regularly.

## **5. Drug Interactions**

- 1) Antiepileptic drugs (phenytoin), barbiturates, and glucocorticoids may reduce the effect of Vitamin D.
- 2) Cholestyramine, colestipol, and orlistat reduce Vitamin D absorption, and in cases of chronic alcoholism, hepatic storage of Vitamin D may also be reduced.
- 3) Thiazide diuretics decrease renal calcium excretion and may cause hypercalcemia. Therefore, during long-term treatment, serum and urinary calcium concentrations should be monitored.

- 4) During administration of Vitamin D, calcium concentration may increase and enhance the toxicity of cardiac glycosides, and arrhythmia may occur. In such patients, ECG should be monitored and serum and urinary calcium concentrations should be observed.
- 5) Aluminum-containing antacids may reduce Vitamin D absorption and decrease the effect of this product, and magnesium-containing preparations may cause hypermagnesemia.
- 6) In animal studies, concomitant administration of calciferol and warfarin increased the effect of warfarin. Therefore, caution should be exercised when this product is administered together with warfarin.

## **6. Use in Pregnant Women**

- 1) Reproductive toxicity studies in animals have not been conducted. Teratogenicity studies in animals have not been conducted.
- 2) High-dose Vitamin D administration during pregnancy may cause fetal harm due to hypercalcemia. Therefore, this product should not be administered to pregnant or breastfeeding women.

## **7. Use in Children**

Safety and efficacy in children under 12 years of age have not been established.

## **8. Treatment of Overdose**

In case of overdose, discontinue administration of Vitamin D and reduce calcium intake. In addition, increase diuresis and increase fluid intake.

## **9. Precautions for Application**

- 1) Do not mix with other medicinal products.
- 2) Use immediately after opening the ampoule and discard any remaining solution.

## **10. Storage and Handling Precautions**

Store at room temperature (1–30°C).

# **Packaging Unit**

5 ampoules/box (1.0 mL per ampoule), 10 ampoules/box (1.0 mL per ampoule), 10 ampoules/box (1.5 mL per ampoule)

# **Manufacturer**

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