

TRICK-D

Oral / I.M.
Ampoule

ٹرک-ڈی

(Colecalciferol BP) (کوئی کیلسیفیرول) اورل/سٹنڈاتی اینیویول
Vitamin D₃

COMPOSITION:

Each 1ml ampoule contains:
Colecalciferol BP (Vitamin D₃) ... 5mg (200,000IU)
[Innovator's Specs.]

DESCRIPTION:

Vitamin D₃ is a fat-soluble vitamin that is essential for maintaining normal calcium metabolism. Chemically it is described as 3-[2-[7a-methyl-1-(6-methylheptan-2-yl)-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidene-cyclohexan-1-ol and its molecular weight is 384.638 g/mol.

PHARMACOLOGY:

Pharmacodynamics: Vitamin D₃ (Colecalciferol) can be synthesized by humans in the skin upon exposure to ultraviolet-B (UVB) radiation from sunlight or it can be obtained from the diet. When exposure to UVB radiation is insufficient for the synthesis of adequate amounts of vitamin D₃ in the skin, adequate intake of vitamin D₃ from the diet is essential for health. Most if not all actions of vitamin D₃ are mediated through a nuclear transcription factor known as the vitamin D receptor (VDR).

Pharmacokinetics: Vitamin D₃ is well absorbed from the gastrointestinal tract. The presence of bile is essential for the adequate intestinal absorption. Absorption may be decreased in patients with decreased fat absorption. Vitamin D₃ and its metabolite circulate in the blood bound to specific alpha globulin. Vitamin D₃ can be stored in muscle and adipose tissue for long periods of time: It is slowly released from such storage sites and from the skin where it is formed in the presence of sunlight or UVB. Vitamin D₃ has a slow onset and longer duration of action. It is hydroxylated in the liver by the enzyme vitamin D 25-hydroxylase to 25-hydroxycolecalciferol (Calcidiol). This compound undergoes further hydroxylation in the kidneys by the enzyme vitamin D 1-hydroxylase to form the active metabolite 1, 25-dihydroxycolecalciferol (Calcitriol). Further metabolism also occurs in the kidney, including the formation of 1,24,25 trihydroxy derivatives. Vitamin D₃ compounds and their metabolites are excreted mainly in the bile and faeces with only small amount appearing in the urine; there is some enterohepatic recycling but it is considered to have negligible contribution to vitamin D₃ status. Certain vitamin D₃ substances may be distributed into the breast milk.

INDICATIONS:

Trick-D injection is indicated:

- For the prevention and treatment of Vitamin D deficiency.
- For the treatment of Vitamin D insufficiency, refractory rickets (Vitamin D resistant rickets), familial hypophosphatemia and hypoparathyroidism and in the management of hypocalcemia and renal osteodystrophy in patients with chronic renal failure undergoing dialysis.
- In conjunction with calcium in the management and prevention of primary or corticosteroid-induced osteoporosis.
- In bone fixation of calcium.

CONTRAINDICATIONS:

The drug must not be used in the following cases:

- Hypersensitivity to any of the ingredients, mainly to vitamin D₃
- Hypercalcemia (abnormally high levels of blood calcium)
- Hypercalciuria (excessive urinary elimination of calcium)
- Calcium lithiasis (kidney stones)

POSSIBLE ADVERSE EFFECTS:

As with any medicine, it may also produce unpleasant effects of varying intensity. Loss of appetite, constipation, diarrhea, dry mouth, headache, increased thirst, mental confusion, nausea & vomiting and unusual tiredness are few of the side effects generally encountered.

DRUG INTERACTIONS:

Steroid medications such as prednisone can interfere with vitamin D₃ metabolism. If you take steroid drugs regularly, discuss with your doctor. The weight loss drug, Orlistat and cholesterol-lowering drug, Cholestyramine may cut absorption of vitamin D₃. People taking these drugs should discuss vitamin intake with their doctors. The seizure drugs Phenobarbital and Phenytoin affect vitamin D₃ metabolism and affect calcium absorption, so do anti-tuberculosis drugs. On the other hand, cholesterol-lowering statin drugs and thiazide diuretics increase vitamin D₃ levels.

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WARNINGS:

Kidney disease: Vitamin D₃ may increase calcium levels and increase the risk of "hardening of the arteries" in people with serious kidney disease.

High levels of calcium in the blood: Taking vitamin D₃ could make this condition worse.

Hardening of the arteries (atherosclerosis): Taking vitamin D₃ could make this condition worse.

Sarcoidosis: Vitamin D₃ may increase calcium levels in people with sarcoidosis. This could lead to kidney stones and other problems.

Histoplasmosis: Vitamin D₃ may increase calcium levels in people with histoplasmosis. This could lead to kidney stones and other problems.

Over-active parathyroid gland (hyperparathyroidism): Vitamin D₃ may increase calcium levels in people with hyperparathyroidism.

Lymphoma: Vitamin D₃ may increase calcium levels in people with lymphoma. This could lead to kidney stones and other problems.

Other medications: Concomitant use of other medicines containing vitamin D₃ could, result in overdosage. If high or repeated doses of vitamin D₃ or calcium are administered, it is necessary to monitor calcium levels in blood and urine.

Pregnancy & Lactation: Vitamin D₃ is SAFE during pregnancy and breast-feeding when used within the recommended dose.

DOSAGE & ADMINISTRATION:

Trick-D can be taken orally or administered by IM route.

Prevention: Infants receiving Vitamin D enriched milk: 1/2 ampoule (2.5 mg or 100000 IU) every 6 months.

Nursed infants or infants not receiving Vitamin D enriched milk or young children upto 5 years of age: 1 ampoule (5 mg or 200000 IU) every 6 months.

Adolescents: 1 ampoule (5 mg or 200000 IU) every 6 months during winters.

Pregnancy: 1/2 ampoule (2.5 mg or 100000 IU) from 6th or 7th month of pregnancy.

Elderly: 1/2 ampoule (2.5 mg or 100000 IU) every 3 months.

Deficiency: 1 ampoule (5 mg or 200000 IU) which can be renewed every 1 to 6 months.

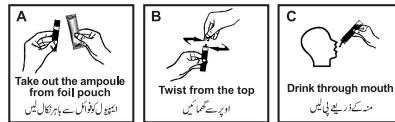
SPECIAL INSTRUCTION TO THE PHYSICIAN:

If high or repeated doses of vitamin D₃ are administered or if high doses of calcium are associated, it is necessary to monitor calcium levels in blood and urine.

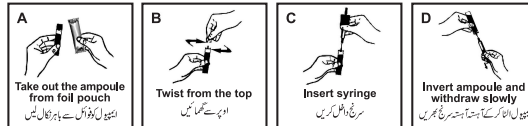
Overdosage: Overdose symptoms may include headache, weakness, drowsiness, dry mouth, nausea, vomiting, constipation, muscle or bone pain, metallic taste in the mouth, weight loss, itchy skin, changes in heart rate, confusion, unusual thoughts or behavior, severe pain in your upper stomach spreading to your back and fainting. Treatment of vitamin D₃ toxicity may include stopping vitamin D supplements and restricting calcium intake as well as taking medication. In severe cases, hospitalization may be necessary.

DIRECTION FOR USE:

Direction for oral use:



Direction for IM use:



INSTRUCTIONS:

Store below 30° C. Protect from heat & light. Keep out of the reach of children.

PRESENTATION: Trick-D ampoule 5mg/ml is available in pack size of 1's x 1ml.

ہدایات: ۱۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی اور روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
Surge Laboratories (Pvt.) Ltd.,
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District Sheikhpura Pakistan.

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