D-Tres® Injection

(Cholecalciferol) Vitamin D_3

Oral / IM use

COMPOSITION:

D-Tres® Injection

Each ml contains:

Cholecalciferol Ph. Eur. .....5mg (200,000 IU)

DESCRIPTION:

Cholecalciferol is the naturally occurring form of vitamin D. It is produced from 7-dehydrocholesterol, a sterol present in mammalian skin, by ultraviolet irradiation

PHARMACOTHERAPEUTIC GROUP:

Vitamin D (Fat soluble vitamin)

PHARMACODYNAMICS:

Vitamin D may have anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant and mood-modulatory activities. Along with parathyroid hormone and calcitonin, regulate serum calcium concentration

PHARMACOKINETICS:

Absorption

Well absorbed from the GI tract. Presence of bile is essential for adequate intestinal absorption. Hence absorption may be decreased in patients with decreased fat absorption

Distribution

Bound to a specific α-globulin. Can be stored in adipose and muscle tissue for long periods of time. Slowly released from storage sites and skin where it is formed in the presence of sunlight or UV light. May distribute into breast milk

Metabolism

Hydroxylated in the liver by the enzyme vitamin D 25-hydroxylase to form 25-hydroxycholecalciferol (calcifediol). Further hydroxylated in the kidneys by the enzyme vitamin D1-hydroxylase to form the active metabolites 1,25-dihydroxycholecalciferol (calcitriol). Further metabolism also occurs in the kidneys, including the formation of the 1,24,25-trihydroxy derivatives

Excretion

Mainly in the bile and feaces with only small amounts appearing in urine

INDICATIONS:

- Bone fixation of calcium
- Prevention and treatment of vitamin D deficiencies

DOSAGE AND ADMINISTRATION:

Infants receiving vitamin enriched milk

½ Ampoule (i.e. 100,000 I.U) every 6 months

Nursed infants or infants not receiving vitamin D enriched milk or young children up to 5 years of age:

1 Ampoule (200,000 I.U) every 6 months

Adolescents

1 Ampoule (200,000 I.U) every 6 months during winter

Pregnancy

½ Ampoule (i.e. 100,000 I.U) from 6th to 7th month of pregnancy

Elderly

½ Ampoule (i.e. 100,000 I.U) every 3 months

Digestive disorders, concomitant treatment with antiepileptics, other particular conditions not described above:

½ or 1 Ampoule every 3 to 6 months

Vitamin D Deficiency

1 Ampoule (200,000 I.U) which can be renewed once 1 to 6 months later

OR

As directed by the physician

SIDE EFFECTS / ADVERSE REACTIONS:

Hyperphosphataemia or hypercalcaemia (in excessive intake). Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, renal and CV damage

PRECAUTIONS:

Excessive intake may lead to development of hyperphosphataemia or hypercalcaemia. Infants, renal impairment or calculi, heart disease. Monitor plasma phosphate and calcium level during pregnancy/lactation

WARNING:

The drug must not be used in the following cases:

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

SPECIAL WARNING:

If high or repeated doses of vitamin D are administered or if high dose of calcium are associated, it is necessary to monitor calcium level in blood and urine

DRUG INTERACTIONS:

Interaction with other medicines and other interactions

Increased risk of hypercalcaemia if given with thiazide diuretics, calcium or phosphate. Antiepileptics (e.g. carbamazepine, phenobarbitone, phenytoin and primidone) may increase vitamin D requirements. Rifampicin and isoniazid may reduce efficacy of vitamin D. Corticosteroids may counteract the effect of vitamin D. Digoxin or any cardiac glycoside reduced absorption when taken with cholestyramine, colestipol, mineral oil, orlistat and ketoconazole

CHOLECALCIFEROL AND PREGNANCY:

Category A: Controlled studies in women fail to demonstrate a risk to the foetus in the 1st trimester (and there is no evidence of a risk in later trimesters), and the possibility of foetal harm remains remote

If dose > US RDA

Category D: There is positive evidence of human foetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective)

OVERDOSE:

In the event of an overdose of vitamin D, following symptoms may occur: headache, fatigue, slimming, growth retardation, nausea, vomiting, excess of urine, intense thirst and arterial hypertension

STABILITY:

See expiry on the pack

AVAILABILITY:

D-Tres® Injection in pack of 1's

D-Tres® Injection in pack of 5's

INSTRUCTIONS:

Keep out of reach of children

Avoid exposure to heat, light and freezing

Store between 15 to 30°C

Improper storage may deteriorate the medicine

Caution:

Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particle(s)

ڈی-ٹریس® انجکشن

(کولی کیلسی فیرول) وٹامن ڈی تھری

اورل/عضلاتی استعمال کیلئے

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

تنبیہ: انجکشن کے لیک ہونے، دُھندلا ہونے یا اس میں کوئی غیر حل پزیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

P001618/S R.N-05/HA/08/15

220 mm

71 mm