ViD-Tres™ Oral Drops

Cholecalciferol

Sugar Free

COMPOSITION

ViD-Tres™ Oral Drops
Each drop contains:
Cholecalciferol (Vit. D3)….400 I.U.

DRUG 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.

CLINICAL PHARMACOLOGY

PHARMACODYNAMICS:
Pharmacotherapeutic group: Vitamin D (Fat soluble vitamin).
Vitamin D may have anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant & mood-modulatory activities. Along with parathyroid hormone & 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 •-globulin. Can be stored in adipose & muscle tissue for long periods of time. Slowly released from storage sites & 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 & faeces with only small amounts appearing in urine.

THERAPEUTIC INDICATIONS

ViD-Tres™ contains cholecalciferol (vitamin D3). It is used in the following conditions:

- Prophylaxis of rickets and osteomalacia (softening or weakening of bones due to a lack of vitamin D) in children and adults.
- Prophylaxis of rickets in preterm newborns.
- Treatment of vitamin D deficiency (including rickets and osteomalacia) in children and adults;
- Prevention of vitamin D deficiency in high-risk patients (including obese patients, patients with difficulties to absorb vitamin D and patients on medications affecting vitamin D metabolism).
- As an adjunct to specific therapy for osteoporosis (disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break) in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

POSOLOGY

Table summarizing the posologies of different indications against patient population.

Paediatric posology			
	Infant (0-2 years)	Children (2-11 years)	Adolescents (12-18 years)
Treatment (for up to 12 weeks)	400-1000 I.U./day eq. to 10-25mcg/day	400-2000 I.U./day eq. to 10-50mcg/day	400-4000 I.U./day eq. to 10-100mcg/day
Prevention / Long term maintenance	200-1000 I.U./day eq. to 5-25mcg/day	400-1000 I.U./day eq. to 10-25mcg/day	400-1600 I.U./day eq. to 10-40mcg/day

Adult posology		
	Adults and the elderly	Pregnancy / breast feeding
Treatment (for up to 12 weeks)	800-4000 I.U./day eq. to 20-100mcg/day	400-4000 I.U./day eq. to 10-100mcg/day
Prevention / Long term maintenance	800-1600 I.U./day eq. to 20-40mcg/day	400 I.U./day (but upto 2000 I.U./day) eq. to 10mcg/day (but upto 50mcg/day)
Adjunct to specific therapy for osteoporosis	800 I.U./day eq. to 20mcg/day	-

* 1 I.U. = 0.025mcg

METHOD OF ADMINISTRATION

ORAL:
The bottle should be held vertically while dispensing drops.

ViD-Tres™ can be dispensed onto a spoon and taken as is or to facilitate the intake, it can also be mixed with a small amount of cold or lukewarm food immediately prior to use. The patient should be sure to take the entire dose.

In infants, children and adolescents ***ViD-Tres™*** can be mixed with a small amount of children's food, yogurt, milk, cheese or other dairy products. ***ViD-Tres™*** must not be mixed into a bottle of milk or container of soft foods in case the child does not consume the whole portion, and consequently does not receive the full dose.

CONTRAINDICATIONS

- Hypersensitivity to vitamin D or any of the excipients in the product.
- Hypervitaminosis D.
- Nephrolithiasis.
- Diseases or conditions resulting in hypercalcaemia and/or hypercalciuria.
- Severe renal impairment.

PRECAUTIONS

Excessive intake may lead to development of hyperphosphataemia or hypercalcaemia. It should be used with caution in infants with renal impairment or calculi or heart disease.

WARNINGS

The drug must not be used in the following cases:

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

DRUG INTERACTIONS

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
Concomitant treatment with phenytoin or barbiturates can decrease the effect of vitamin D because of metabolic activation. Concomitant use of glucocorticoids can decrease the effect of vitamin D. The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with Vitamin D. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium.

Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.
The cytotoxic agent actinomycin and imidazole antifungal agents interfere with vitamin D activity by inhibiting the conversion of 25-hydroxyvitamin D to 1,25- dihydroxyvitamin D by the kidney enzyme, 25-hydroxyvitamin D-1-hydroxylase.

FERTILITY, PREGNANCY AND LACTATION: There are no or limited amount of data from the use of cholecalciferol in pregnant women. Studies in animals have shown reproductive toxicity .The recommended daily intake for pregnant women is 400 I.U., however, in women who are considered to be vitamin D deficient a higher dose may be required. During pregnancy women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment.
Vitamin D and its metabolites are excreted in breast milk. Overdose in infants induced by nursing mothers has not been observed, however, when prescribing additional vitamin D to a breast-fed child the practitioner should consider the dose of any additional vitamin D given to the mother.

SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Vitamin D can cause the following undesirable effects, especially in overdose:

Metabolism and nutrition disorders: Too high calcium levels in blood and urine (hypercalcaemia, hypercalciuria).
Gastrointestinal disorders: Constipation, bloating, feeling sick, stomach-ache, diarrhoea.
Frequency of the occurrence of the above mentioned side effects is not known (cannot be estimated from the available data).

STABILITY

See expiry on the pack.

AVAILABILITY

ViD-Tres™ Oral drops in a pack of 10ml

INSTRUCTIONS

Dosage as advised by the Healthcare Professional.
Keep out of reach of children.
Avoid exposure to heat, light and freezing.
Store below 30°C.

Dietary Supplement: As per drug Act 1976, this product is not an allopathic drug.

Please read the contents carefully before use.
This package insert is regularly reviewed and updated.

DRAP Enlistment No. 00174
Mfd. by: Hiranis Pharmaceuticals (Pvt) Ltd.
E-145-149, North Western Industrial Zone,
Port Qasim, Karachi-75020, Pakistan

Mktd. by:
Phytek (Pvt.) Ltd.
85-B, M.M.A.C.H.S., Karachi

An associate company of:
SAMI Pharmaceuticals (Pvt.) Ltd.
Karachi-Pakistan
www.samipharmapk.com

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کولی کیلسی فیرول

خوراک: معالج کی ہدایت کے مطابق استعمال کریں۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کو دھوپ، گرمی اور منجمد ہونے سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

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