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Vidrop

COMPANY NAME: Medical Union Pharmaceuticals
TRADE NAME: Vidrop
FORM: oral solution
Vidrop is a stabilized aqueous solution of vitamin D_3 (cholecalciferol).

COMPOSITION
Each 1 ml (=28 drops) oforal solution contains:
Vitamin D_3 (cholecalciferol) 2800 IU,
(each drop contains 100 IU of vitamin D_3).
Excipients: polysorbate 20, vitamin E, glycerin, disodium edetate, β-cyclodextrin, purified water.

PROPERTIES/ACTIONS
Vitamin D, which is effective in therapeutic use when given orally is a naturally occurring hormone in humans, being formed from 7-dehydrocholesterol in the skin as a result of exposure to sunlight (ultraviolet irradiation). It is also obtained in a small quantities from dietary source such as milk, butter, liver and egg yolks. Vitamin D regulates calcium and phosphate metabolism, its main function being to mediate intestinal calcium absorption by an active transport mechanism. It also promotes normal bone formation. The minimum daily requirement of vitamin D is100-400IU,depending on age.

PHARMACOKINETICS
Vitamin D_3 is rapidly absorbed from the proximal and distal small intestine and transported to its main storage sites (liver and adipose tissue) bound to specific α-globulins.
Vitamin D_3 is biotrans formed in the liver to 25-hydroxycholecalciferol (25-HCC, calcifediol), which then undergoes further hydroxylation at position 1 in the kidneys to give the active metabolite 1,25-dihydroxycholecalciferol(1,25-DHCC;calcitriol). Vitamin D is stored in the body and excreted mainly in the form of inactive glucuronides. It is excreted both in faeces via the bile and in urine.

INDICATIONS / USES
- Prevention of rickets
- Treatmentof all forms and stages of rickets
- Osteomalacia
- Acute postoperative hypoparathyroidism
- Chronic hypoparathyroidism

DOSAGE/ADMINISTRATION
Prevention of rickets:
- Full-term infants:
400 IU (= 4 drops) daily in thefirstyearof life, starting in week 2-5.
- Preterm infants: 400-800 IU (= 4-8drops) dailyin thefirstyearof life.

Treatment of rickets: Dosage should be individualized on the basis of frequent determinations of serum calcium and bone X-rays.
Florid rickets: 5000 IU (= 50 drops) dailyforthree weeks.

INSTRUCTIONS FOR USE OF THE ORAL SOLUTION
Add the required numberof drops to food or drink.

RESTRICTIONS ON USE
Contraindications
To use Vidrop for rickets prevention in infants: hypothyroidism, idiopathichypercalcaemia, vitamin-D hypersensitivity.
To high dose of vitamin-D therapy in adults: skeletal disorders involving complete immobilization (which increase calcium excretion), sarcoidosis (Boeck`s disease), acute pulmonary tuberculosis, immobilization following corrective orthopedic surgery.
Vidropshould notbe given by I.V. injection.
Concomitant administration of vitamin-D analogues.

PRECAUTIONS
- Caution is required in patients with disturbances of calcium metabolism, Kidney failure, kidney stones, arteriosclerosis or coronary disease.
All forms of vitamin D are toxic in high doses, causing a significant increase in calcium absorption. Toxic effects may also occur if doses of 1000-3000 IU /kg body weight daily are administered over a period of several months.
- The fact that milk, fats and baby foods or other foods are often enriched with vitamin D should be taken into account when determining dosage.
- Caution should be exercised in patients receiving treatment with cardiac glycosides since hypercalcaemia may lead to arrhythmia in suchcases.
Particular care should be taken to avoid the following:
- Prophylactic administration of vitamin D in large doses over a period of months or even years without proper monitoring or a specific indication especially in conjunction with calcium and /or vitamin-enriched foods (e.g. baby foods).
- Massive doses of vitamin D at short intervals.This is because the body's attempts to eliminate the resultant calcium excess might overload the excretory capacity of the Kidneys; the first symptoms of overdosage are polyuria and Polydipsia.
- Patients receiving the recommended dose of Vidrop for the prevention of rickets or osteomalacia or as a supplement to the normal diet should avoid otherdrugs containing vitamin D and vitamin-D enriched foods.
- Particular care should be exercised in the prophylactic use of vitamin-D preparations in infants receiving vitamin-D enriched baby foods (normallycontaining400 IU perdaily portion).
- The recommended dose should be taken regularly but not exceeded.
- Care should be taken for patients receive sufficient dietary calcium regular blood calcium checks should be performed on patients r eceiving long-termtreatment forvitamin D-resistant rickets.

PREGNANCY AND LACTATION
Vidrop may be taken by women who are pregnant or breastfeeding at a dosage corresponding to the normal daily requirement. There is clear evidence that doses in excess of the daily requirement represent a risk to the foetus, although this may be outweighed by the therapeutic benefit to the mother.

ADVERSE REACTIONS
In recommended daily allowance, adverse effects are very rare; these may include mild gastrointestinal symptoms.

INTERACTIONS
- Colestyramine, colestipol and mineral oils may reduce the intestinal absorption of vitamin D and as long an interval as possible (atleast 4 hours) should therefore beallowedbetween ingestion.
- Concomitant administration with thiazide diuretics may lead to hypercalcaemia, possibly necessitating the withdrawal of Vidrop.
- Phenobarbital and phenytoin (and presumablyother liver-enzyme-inducing agents) maycausea reduction in plasma levelsof cholecalciferol.
- Corticosteroids may lessen the effect of cholecalciferol.
- Concomitant administration with cardiac glycosides may result in cardiacarrhythmia.

OVERDOSAGE
If vitamin D overdosage exceeds the excretory capacity of the kidneys, calcium deposits may be formed in the kidneys and vascular walls,
The signs and symptoms of overdosage are thirst, polyuria, loss of appetite, nausea, vomiting, constipation, headache, joint pain, muscle weakness, dehydration (especially wizened, dry skin in children), tremor affecting the extremities, muscular atrophy with fibrillary contractions and hypertension. These symptoms are reversible providedvitamin D is withdrawn intime.

MANAGEMENT
Immediate discontinuation of all vitamin D intake, increase of fluid intake and avoidance of calcium-rich foods.
Additionally in severe cases prednisolone 25 mg i.v. then 10 mg /day by mouth.

OTHER INFORMATION
Note Likeall drugs, Vidropshould be keptoutof reach of children.

SHELF-LIFE
The drug should not be used afterthe expirydate (=EXP) printed on the pack.
Store oral solution at a temperature not exceeding 30°C, away from light.

PACK
Carton box containing glass bottle type III of 10 or 15 ml with plastic dropper with white cap and off/ white rubber pump and inner leaflet.

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children.

Council at Arab Health Ministers Union at Arab Pharmacists

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