VIDELTA
VITAMIN D3
(Cholecalciferol)
INJECTION IM/Oral

200,000 IU
INJECTION

۲۰۰،۰۰۰ آئی یو
انجیکشن

وی ڈیلٹا
وٹامن ڈی ۳ (کولیکیلسیفرول)
اول/عضلاتی انجیکشن

VA-LA-P-001

1. Composition
Each ml contains:
Cholecalciferol (Vitamin D3) B.P. …….. 5mg (200,000IU)

2. Description
Cholecalciferol, also known as Vitamin D3, is automatically produced by the skin when it is exposed to direct sunlight. It is an important nutrient required for bones & teeth and a sufficient amount of it must be present in our body as it helps in the absorption of calcium. It helps to make bones strong and prevents various bone disorders such as rickets, arthritis and osteomalacia. It also helps to boost the immune system and may reduce the risk of cancer as well. Its molecular formula is $C_{27}H_{44}O$.

3. Therapeutic Indications
Prophylaxis and/or treatment of vitamin D deficiency symptoms e.g., malabsorption by chronic intestinal diseases, biliary hepatocirrhosis, extended stomach, or intestinal resections.

4. Dosage & Method of Administration
Dosage:
1 ampoule contains 200,000 IU of vitamin D3.
Dosage
Prophylaxis
VIDELTA, IM injectable solution in ampoule is not suitable for the prophylaxis of vitamin D deficiency in children in the general population.
Child or adult with a digestive pathology (intestinal malabsorption and cystic fibrosis): ½ to 1 ampoule (i.e. 100,000 to 200,000 IU) every 3 months.
Child or adult receiving anticonvulsant treatment: ½ to 1 ampoule (i.e. 100,000 to 200,000 IU) every 3 months.
Child or adult under the following conditions:
- No sun exposure or strong skin pigmentation with:
- Unbalanced diet (low in calcium, vegetarian)
- Or extensive dermatological pathology
- Or granulomatous disease (tuberculosis, leprosy)
- Subjects receiving long-term corticosteroid therapy
- Liver failure.

1 ampoule (i.e. 200,000 IU) every 6 months.
In elderly subjects: ½ ampoule (i.e. 100,000 IU) every 3 months.
Treatment of vitamin D deficiency (rickets, osteomalacia, neonatal hypocalcemia): 1 ampoule (i.e. 200,000 IU) possibly repeated once after 1 to 6 months.
Method of administration
- Intramuscular (IM) route: Administer by intramuscular injection.
- Oral route: The contents of the ampoule may also be administered orally using the provided straw, either directly or mixed into a small quantity of liquid or semi-liquid food.

5. Contraindications
VIDELTA may not be used when,
- Hypersensitivity against any ingredients, Hypercalcemia and/or hypercalciuria, Kidney insufficiency or renal impairment.

6. Warnings & Precautions
A special caution is appropriate with patients
- whose mobility is restricted (e.g., by cast),
- who are treated with derivatives of benzothiadiazine,
- with kidney stone anamnesis,
- with sarcoidosis (risk of transformation of vitamin D into its active metabolites is increased)
- with pseudohypoparathyroidism.

7. Adverse Effects
A heavy and long-lasting hypercalcemia can appear depending on dosage and duration of therapy, with its acute symptoms (arrhythmias, nausea, vomiting, psychic symptoms, impaired renal function and chronic symptoms polyuria, polydipsia, inappetence, weight loss, kidney stone formation, nephrocalcinosis, extraosseous calcifications).

8. Reporting of Side Effects
If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via https://bfbio.com/drug-safety/. By reporting side effects, you can help provide more information on the safety of this medicine

9. Drug Interactions
- Thiazide diuretics can lead to hypercalcemia by the reduction of the renal calcium excretion. The calcium levels in the plasma and in the urine should there-fore be supervised during a long-term therapy.
- Phenytoin or barbiturates can impair the effect of vitamin D3.
- The simultaneous administration of glucocorticoids can reduce the effect of vitamin D3.
- The toxicity of cardiac glycosides can be increased during the therapy with vitamin D because of increased calcium levels (risk for arrhythmias). Patients should be supervised with regard to ECG and calcium levels in the plasma and in the urine.
- Only in exceptional cases and under serum calcium controls, VIDELTA should be combined with metabolic products or analogues of vitamin D.

10. Pregnancy & Lactation
Cholecalciferol can be prescribed during pregnancy & to nursing mothers, if necessary, when used in daily amounts below 2000 IU.

11. Clinical Pharmacology
Mode of action
Vit D may have anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant & mood-modulatory activities. Along with parathyroid hormone & calcitonin, regulate serum calcium conc. The onset is slow while relatively prolonged duration of action.

12. Overdose
Symptoms
In the event of an overdose, the symptoms that may occur include headache, fatigue, weight loss, growth retardation, anorexia, drowsiness, dry skin, itchy skin, nausea, vomiting, constipation, muscle or bone pain, metallic taste in the mouth, hypercalcemia, hypercalciuria, hyperphosphatemia, hyperphosphaturia, intense thirst, polyuria, arterial hypertension, dehydration, and severe pain in upper stomach spreading to back or fainting.
Treatment
Overdosage can be treated by discontinuing administration of cholecalciferol, increasing diuresis or by increasing the administration of fluids.

13. Special Precautions for Handling and Disposal
- Ensure the ampoule is properly positioned in its plastic body cover with the cracker correctly fitted.
- Gently tap the ampoule to ensure the liquid flows into the body.
- Hold the plastic cover firmly and use the provided ampoule cracker to open the ampoule with steady, controlled pressure. Hold the ampoule in your left hand and apply pressure with your right thumb on the cracker while gently twisting your index finger to break the ampoule.
- Avoid twisting, excessive force, or direct contact with broken glass edges.
- Dispose of broken glass in an appropriate sharps container and plastic components according to applicable waste-disposal procedures.

14. Storage and Instructions
- Keep in dark, cool and dry place below 25°C.
- Keep out of the reach of children.
- Improper Storage may deteriorate the product.
- To be sold on the prescription of the registered medical practitioner.

15. Other Information
What Videlta contains
The active substance is cholecalciferol (vitamin D3).
Each ml contains:
Cholecalciferol (Vitamin D3) B.P. …….. 5mg (200,000IU)
What Videlta looks like
Videlta is solution for injection, for oral or intramuscular use, supplied in a glass ampoule fitted with a plastic body cover, a plastic ampoule cracker, and a straw for oral administration.

Manufactured by:
BF BIOSCIENCES
BF BIOSCIENCES LIMITED
(A Subsidiary of FEROZSONS LABORATORIES LIMITED)
5-KM, Sundar Raiwind Road, Raiwind, Lahore, Pakistan.
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