

**Package leaflet:** Information for the patient

## D-Vital 10,000 I.U. hard capsules

Cholecalciferol (Vitamin D3)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### What is in this leaflet

1. What D-Vital is and what it is used for

2. What you need to know before you take D-Vital

3. How to take D-Vital

4. Possible side effects

5. How to store D-Vital

6. Contents of the pack and other information

#### 1. What D-Vital is and what it is used for

D-Vital contains the active substance cholecalciferol (also known as vitamin D3).

Vitamin D3 is essential to maintain normal blood levels of calcium. It aids in the absorption of calcium, helping to form and maintain strong bones. Vitamin D can be found in some foods and is also produced by the body when skin is exposed to sunlight.

This medicine is used alone or in combination with calcium for the prevention and treatment of vitamin D deficiency.

#### 2. What you need to know before you take D-Vital

##### Do not take D-Vital:

- If you are allergic (hypersensitive) to cholecalciferol or any of the other ingredients of this medicine (listed in section 6).

- If you have high levels of calcium in your blood (hypercalcemia) or urine (hypercalciuria).

- If you have severe kidney problems.

- If you have a tendency to form calcium containing kidney stones.

- If you have high levels of vitamin D in your blood (hypervitaminosis D).

##### Warnings and precautions:

Check with your doctor or pharmacist before taking your medicine if any of the following apply to you:

- Are undergoing treatment with certain medicines used to treat heart disorder (e.g. cardiac glycosides, such as digoxin).

- Have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body).

- Are taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D.

- Are likely to be exposed to a lot of sunshine whilst using D-Vital.

- Take additional supplements containing calcium. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are using D-Vital.

- Have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

### Other medicines and D-Vital:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Taking some medicines together can be harmful. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines that act on the heart or kidneys, such as cardiac glycosides (e.g. digoxin) or diuretics (e.g. bendroflumethiazide). When used at the same time as vitamin D these medicines may cause a large increase in the level of calcium in the blood and urine.
- Medicines containing vitamin D or eating food rich in vitamin D, such as some types of vitamin D-enriched milk.
- Actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g. clotrimazole, medicines used to treat fungal disease). These medicines may interfere with the way your body processes vitamin D.
- The following medicines because they can interfere with the effect or the absorption of vitamin D:
  - Antiepileptic medicines (such as phenytoin) or medicines to treat sleep disorders and epilepsy (barbiturates such as phenobarbitone).
  - Glucocorticoids (steroid hormones such as hydrocortisone and prednisolone). These can decrease the effect of vitamin D.
  - Medicines that lower the level of cholesterol in the blood (such as cholestyramine or colestipol).
  - Certain medicines for weight loss that reduce the amount of fat your body absorbs (such as orlistat).
  - Certain laxatives (such as liquid paraffin).

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

#### Taking D-Vital with food and drink

You can take D-Vital with or without food and drink.

#### Pregnancy and breast-feeding:

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will recommend the dose based on your needs.

#### Driving and using machines:

D-Vital should not affect your ability to drive or use machines.

#### Important information about some of the ingredients of D-Vital:

This medicine contains sucrose therefore if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking it.

#### 3. How to take D-Vital

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dose and duration of treatment depend on the severity of the deficiency and the level of vitamin D in your blood.

#### Use in adults

The usual dose for the prevention of Vitamin D deficiency is 1 capsule (10,000 I.U.) taken orally, once a week for a duration specified by your doctor. In case of malabsorption syndrome, the dose can be adjusted

to 1 capsule (10,000 I.U.) taken orally, once a day.

Your doctor may recommend other doses based on your needs.

The usual dose for the treatment of vitamin D deficiency is 1 capsule (10,000 I.U.) taken orally once a day for a duration specified by your doctor. In case of malabsorption syndrome or hepatobiliary disease, the dose can range from 1 to 5 capsules (10,000 to 50,000 I.U.) taken orally once a day for a duration specified by your doctor.

Your doctor may recommend other doses based on your needs. The dose of 10,000 I.U. per day is safe for 5 months.

The doctor must decide on an individual basis whether any further treatment (follow-on or long-term) with D-Vital is necessary.

During long-term treatment, the calcium levels in the blood and urine should be monitored regularly and kidney function tested by measurement of serum creatinine. If necessary, the dosage must be adjusted according to the blood calcium values (see Warnings and Precautions Section).

#### Use in children and adolescents

The usual dose for the treatment of vitamin D deficiency is 1 to 2 capsules (10,000 I.U. – 20,000 I.U.) orally once a day, for a duration specified by your doctor or your doctor may recommend another dose based on your needs.

For the prevention of vitamin D deficiency, your doctor will recommend the dose based on your needs. For a child under 12 years as they may not be able to swallow the capsules, it is recommended to empty the capsule content in a full glass of water or juice and drink immediately.

#### If you take more D-Vital than you should

If you accidentally take too many capsules, or someone else takes any of your medicine, you should tell your doctor at once or contact the nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

An overdose can lead to increased levels of calcium in the blood (hypercalcemia) and in the urine (hypercalciuria), shown by lab tests. Signs and symptoms of an overdose can be nausea (feeling sick), vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration.

Your doctor will treat you accordingly in case of an overdose.

#### If you forget to take D-Vital

If you miss a dose, take it as soon as you remember within the same day.

If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule.

Do not take a double dose to make up for a forgotten capsule.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects may include:

Uncommon: Too much calcium in your blood (hypercalcemia): you may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion, and too much calcium in your urine (hypercalciuria).

Rare: Skin rash, itching, and hives.

#### Additional side effects in children

Infants and children may be more hypersensitive to vitamin D. Hypervitaminosis D and hypercalcemia may occur at relatively low doses.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### 5. How to store D-Vital

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.

- Do not store above 30°C. Keep away from light and humidity.

- Do not use this medicine if you notice visible signs of deterioration.

- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What D-Vital capsules contains

- The active substance is cholecalciferol (also known as vitamin D3). Each D-Vital 10,000 I.U. capsule contains cholecalciferol equivalent to 0.25 mg of vitamin D3.

- The other ingredients are DL-alpha-tocopherol, sucrose, silicon dioxide, medium chain triglycerides, starch and sodium ascorbate crystalline.

- The capsule shell contains gelatine, erythrosine (E127), indigo carmine (E132) and titanium dioxide (E171).

##### What D-Vital capsules looks like and contents of the pack

D-Vital capsules are red and white hard capsules.

D-Vital is available in boxes containing 30 capsules.

##### Marketing Authorisation Holder and Manufacturer

Pharmaline – Lebanon

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Contact us: pharmaline@mailiagroup.com

Reg. No. for D-Vital 10,000 I.U. : 97235/12

##### This is a medication

- A medication 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 medication.
- 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.

Council of Arab Health Ministers  
Union of Arab Pharmacists

**This leaflet was last revised in June 2018.**