

# D<sub>3</sub> Max

Vitamin D<sub>3</sub>

**TQ PHARMA**  
Total Quality  
شركة تقدم للمستعات المعاشرة  
Al-Taqaddum Pharmaceutical Industries

## Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What D<sub>3</sub> MAX is and what it is used for.
2. Before you take D<sub>3</sub> MAX
3. How to take D<sub>3</sub> MAX
4. Possible side effects.
5. How to store D<sub>3</sub> MAX
6. Further information.

### 1. What D<sub>3</sub> MAX is and what it is used for:

**Pharmacotherapeutic group:**  
Vitamin D and analogue, ATC code: A11CC05.

### Therapeutic indications:

- D<sub>3</sub> MAX is used for the:
- Treatment and prevention of vitamin D deficiency states and hypocalcemia in disorders such as hypoparathyroidism.
  - Treatment of hypoparathyroidism in pregnancy.
  - Treatment of osteomalacia and rickets.
  - Treatment and prevention of osteoporosis (in conjunction with calcium).
  - Prevention of corticosteroid induced osteoporosis.
  - Prevention of fractures.
  - Prevention of various cardiovascular, metabolic disorders including diabetes mellitus, multiple sclerosis and malignant disorders.

### 2. Before you take D<sub>3</sub> MAX:

- a. Do not Take D<sub>3</sub> MAX:**
- Hypersensitivity to vitamin D or any of the excipients in D<sub>3</sub> MAX.
  - Peanut or soya allergy.
  - Hypervitaminosis D.
  - Nephrolithiasis.
  - Diseases or conditions resulting in hypercalcemia and/or hypercalciuria.
  - Severe renal impairment.

**b. Take special care with D<sub>3</sub> MAX:**

- Vitamin D3 should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account.
- In patients with severe renal insufficiency, vitamin D in the form of Cholecalciferol is not metabolized normally and other forms of vitamin D should be used.
- Caution is required in patients receiving treatment for cardiovascular diseases.
- Vitamin D3 should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of vitamin D to its active form. These patients should be monitored

with regard to the calcium content in serum and urine.

- Allowances should be made for vitamin D supplements from other sources.
- The need for additional calcium supplementation should be considered for individual patients. Calcium supplements should be given under close medical supervision.
- Medical supervision is required whilst on treatment to prevent hypercalcemia.
- Vitamin D<sub>3</sub> capsules should not be given to children.

### c. Taking other medicines, herbal or dietary supplements:

- 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-dihydroxy vitamin D by the kidney enzyme, 25-hydroxy vitamin D-1-hydroxylase.

### d. taking with food and drink:

Vitamin D substances are well absorbed from the gastrointestinal tract. The process of bile is essential for adequate intestinal absorption;

absorption may be decreased in patients with decreased fat absorption.

**D<sub>3</sub> MAX (Cholecalciferol)** has a slow onset and long duration of action. It is hydroxylated in the liver and kidney.

### e. Pregnancy and breast-feeding:

#### Pregnancy

Hypercalcemia during pregnancy may produce congenital disorders in the offspring, and neonatal hypoparathyroidism; however the risk to the fetus of untreated maternal hypoparathyroidism are considered greater than the risk of hypercalcemia due to vitamin D therapy.

#### Breast-feeding

Vitamin D is distributed into breast milk, and its concentration appears to correlate with the amount of vitamin D in the serum of exclusively breast-fed infants. The American Academy of pediatrics considers the use of vitamin D to be usually compatible with breast feeding, although they recommend, if the mother is taking pharmacological doses of vitamin D, that the infant be closely monitored for hypercalcemia or clinical manifestations of vitamin D toxicity.

- Dose should be monitored by testing for serum vitamin D level.

### 3. How to take D<sub>3</sub> MAX:

Always take D<sub>3</sub> MAX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

D<sub>3</sub> MAX should be swallowed whole (not chewed) with water.

#### Severe vitamin D deficiency:

Serum 25-hydroxyvitamin D level <10 ng/ml (<25 nmol/L). Dosage regimen: Loading dose: D<sub>3</sub> MAX 50,000 I.U. once weekly for 2 to 3 months.

Maintenance dose: D<sub>3</sub> MAX 800 to 2000 I.U. once daily regardless of dosing pattern.

#### Vitamin D Deficiency:

Serum 25-hydroxyvitamin D level 10-15 ng/ml (25-37 nmol/L). Dosage regimen: D<sub>3</sub> MAX 2000-5000 I.U. once daily, or 5000 I.U. once daily.

Blood testing Every 6 months, or every 2-3 months.

**Vitamin D Insufficiency:** Serum 25-hydroxyvitamin D level 15-30 ng/ml (37-75 nmol/L). Dosage regimen: D<sub>3</sub> MAX 2000-5000 I.U. once daily, or 5000 I.U. once daily.

Blood testing Every 6 months, or every 2-3 months.

#### supplementation:

1000-2000 I.U. once daily

#### If you take more D<sub>3</sub> MAX S.G capsule than you should:

If you take more D<sub>3</sub> MAX than prescribed by your doctor, talk to your doctor or pharmacist straight away. Excessive intake of vitamin D leads to the development of hyperphosphatemia or hypercalcemia. Associated effects with hypercalcemia include

hypercalcemia, ectopic calcification, renal and cardiovascular damage, muscle weakness, apathy, headache, anorexia, nausea, vomiting, bone pain, proteinuria and hypertension. Chronic hypercalcemia can lead to generalized vascular calcification, nephrocalcinosis and rapid deterioration of renal function. Hypercalcemia has been reported in a patient after brief industrial exposure to cholecalciferol.

#### Sign and symptoms:

Anorexia, lassitude, nausea and vomiting, constipation, or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo. Infant and children are generally more susceptible to its toxic effect. The vitamin should be withdrawn if toxicity occurs. It has been stated that vitamin D dietary supplementation may be detrimental in persons already receiving an adequate intake through diet and exposure to sunlight, since the difference between therapeutic and toxic concentrations is relatively small.

#### If you forget to take D<sub>3</sub> MAX

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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

#### 4. Possible side effects

Like all medicines, D<sub>3</sub> MAX can cause side effects, although not everyone gets them.

The majority of all adverse reactions

- Metabolism and nutrition disorders: Hypercalcemia and hypercalcuria.

- Skin and subcutaneous disorders: Pruritis, rash and urticaria.

If any of the side effects gets serious, or if you note any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### 5. How to store D<sub>3</sub> MAX

- Keep the medicine out of the reach of children.

- Do not store above 30°C.

- store in a cool & dry place away from direct light.

- The validity date which written after the EXP on the carbon indicates the last day of the month.

- D<sub>3</sub> MAX does not require any special storage conditions.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. Further information

#### a. What D<sub>3</sub> MAX contains:

The active substance is:

Cholecalciferol.

**D<sub>3</sub> MAX 10,000:** Each capsule contains 10,000 IU equivalent to 0.25mg Vitamin D3 (Cholecalciferol) in packs of 10, 20, 30 Capsules.

**D<sub>3</sub> MAX 50,000:** Each capsule contains 50,000 IU equivalent to 1.25mg Vitamin D3 (Cholecalciferol) in packs of 8, 10, 12, 20, 30 Capsules. Hospital packs are also available (500, 1000).

Note: not all strengths are available in all markets.

Not all pack sizes are available in all countries.

#### b. Physical description:

**D<sub>3</sub> MAX 10,000:** orange colored, clear transparent round shaped gelatin capsules with aclear colorless liquid fill.

**D<sub>3</sub> MAX 50,000:** Yellow colored transparent round shaped gelatin capsules with aclear colorless liquid fill.

**D<sub>3</sub> MAX (10,000 and 50,000 )** is supplied in PVC/PVDC- Aluminium blisters, in carton box with afoled leaflet.

#### The other ingredients are:

Medium chain triglycerides, vitamin E, gelatin 160 bloom, glycerine, sorbitol liquid, partially dehydrated (polysorb® 85/70/00), quinoline yellow and purified water.

**c. Pharmaceutical form:** Soft gelatin capsule.

#### c. Marketing Authorization Holder and Manufacturer:

Al-Taqaddum Pharmaceutical Industries.

Almwaqqar – Amman, Jordan

Tel.: +962-6-4050092

Fax: +962-6-4050091

P. O. Box: 1019 Amman 11947

Jordan

Email: info@tqpharma.com

d. This leaflet was last approved in 12/ 2019; version number: I-0061-DMX-LMO-R1/AE

#### 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 the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS  
UNION OF ARAB PHARMACISTS

2642

2642

Dimension 24 X 15cm black

