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Hi Dee® Soft Gelatin Capsules

Vitamin D3 (Cholecalciferol)

Read all of this leaflet carefully before you start using 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 inform your doctor or pharmacist.

What is in this leaflet:

1. What **Hi Dee®** is and what it is used for
2. Before you take **Hi Dee®**
3. How to take **Hi Dee®**
4. Possible side effects
5. How to store **Hi Dee®**
6. Further information

1. What Hi Dee® is and what it is used for

Hi Dee® capsules contain the active substance cholecalciferol (vitamin D3).
Vitamin D is found in the diet and is also produced in the skin after exposure to the sun. Vitamin D3 regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.
Often vitamin D is given in combination with calcium.
Cholecalciferol capsules may be prescribed by your doctor to treat or prevent vitamin D deficiency. Deficiency of vitamin D may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D (for instance when you are pregnant).
Vitamin D substances are well-absorbed from the gastrointestinal tract. The presence of bile is essential for adequate intestinal absorption; absorption may be decreased in patients with decreased fat absorption.
Hi Dee® (Cholecalciferol) has a slow onset and a long duration of action. It is hydroxylated in the liver and kidneys.
Indications:
- 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.
- Normalize vitamin D metabolism in the pregnant women and their neonates.

2. Before you take Hi Dee®

Do not use Hi Dee®
• If you are allergic to cholecalciferol, or any other ingredients in this medicine.
• If you have high blood levels of calcium (hypercalcemia) or vitamin D (hypervitaminosis D)
• if you have high blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria);
• if you have kidney stones or serious kidney problems.

If any of the above applies to you, do not take Cholecalciferol capsules.

Take special care with Hi Dee®
- Vitamin D should be used with caution in infants, who may have increased sensitivity to its effects, and in patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcemia occurred.
- Plasma phosphate concentrations should be controlled during vitamin D therapy to reduce the risk of ectopic calcification.
- It is advised that patients receiving pharmacological doses of vitamin D should have their plasma calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity, and in infants, if they are breast-fed by mothers receiving pharmacological doses of vitamin D.
- Dose should be monitored by testing for serum vitamin D level.

Talk to your doctor or pharmacist before taking **Hi Dee®** capsules:
o if you have kidney damage or disease and long term treatment with this medicine. Your doctor may want to measure the levels of calcium in your blood or urine;
o if you are being treated for heart disease;
o you have sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes);
o if you are already taking additional doses of calcium or vitamin D. Whilst you are taking Cholecalciferol capsules your doctor will monitor your blood levels of calcium to make sure they are not too high.

Taking Hi Dee® with other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular the following medicines may interact with Cholecalciferol capsules:
• Heart medicines (cardiac glycosides such as digoxin).Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood.
• Thiazide diuretics (used to treat high blood pressure) reduce the urinary excretion of calcium and can increase risk of hypercalcaemia.
• Medicines used to treat epilepsy (such as phenytoin) or medicines to make you sleep (barbiturates such as phenobarbitone) can decrease the effects of vitamin D.
• Glucocorticoids (steroid hormones such as hydrocortisone or prednisolone) can decrease the effects of vitamin D.
• Laxatives (such as paraffin oil), or a cholesterol lowering drug (colestyramine, colestipol), orlistat may reduce the absorption of vitamin D.
• Actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (medicines such as clotrimazole and ketoconazole used to treat fungal diseases) may interfere with the metabolism of vitamin D.
• Calcium, or phosphate: Increased risk of hypercalcemia. Plasma calcium concentrations should be monitored.
• Rifampicin and isoniazide: Rifampicin and isoniazide may reduce the effectiveness of vitamin D.
• Corticosteroids: Corticosteroids may counteract the effect of vitamin D.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking cholecalciferol (vitamin D3), call your doctor.
Pregnancy: Hypercalcemia during pregnancy may produce congenital disorders in the offspring and neonatal hypoparathyroidism. However, the risks to the fetus of untreated maternal hypoparathyroidism are considered greater than the risks of hypercalcemia due to vitamin D therapy.
Breastfeeding: 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 breastfeeding, 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.

Taking Hi Dee® with food
Vitamin D substances are well absorbed from the gastrointestinal tract. The presence of bile is essential for adequate intestinal absorption; absorption may be decreased in patients with decreased fat absorption.

Important information about some of the other ingredients of Hi Dee®
Hi Dee® Capsules contain Arachis oil (peanut oil). If you are allergic to peanut or soya, do not use this medicinal product.
Hi Dee® 10.000IU Capsules contain Red number 33 which may cause allergic reactions.

3. How to take Hi Dee®

Always take **Hi Dee®** exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider, or pharmacist if you are not sure.

Dosage & administration:

Classification	Serum 25-hydroxyvitamin D level	Dosage regimen	Blood testing
Severe vitamin D deficiency	< 10 ng/ml (< 25 nmol/L)	Loading doses: 50,000 I.U. - 60,000 I.U. once weekly for 2 to 3 months. Or 50,000 I.U. 3 times weekly for 1 month. Maintenance dose: 800 to 2000 I.U: once daily, or 60,000 I.U. once per month.	
Vitamin D deficiency	10 –20 ng/ml (25 –50 nmol/L)	2000 – 5000 I.U. once daily Or 10,000 I.U. every other day	Every 6 months Every 2 – 3 months
Vitamin D insufficiency	21-30 ng/ml (52.5– 75 nmol/L)	2000 – 5000 I.U. once daily Or 10,000 I.U. every other day	Every 6 months Every 2 – 3 months
Supplementation	-	1000-2000 I.U. once daily, or 60,000 IU once per month	-

• The variation of laboratory results from lab to lab has to be taken into account. Vitamin D sufficiency is defined as serum 25(OH) D level of 30 to 100 ng/ml (75-250 nmol/L).
• In obese patients, patients with malabsorption syndromes, and patients on medications affecting vitamin D metabolism, a higher dose (two to three times higher dose) of vitamin D is required to maintain a 25(OH)D level above 30 ng/ml, those patients are requested to perform 25(OH)D level lab test on monthly basis.
• Pregnant and Lactating women require 2000 – 4000 I.U. /d to maintain a blood level of 25(OH) D above 30 ng/ml.
Hi Dee® 2000 I.U. Capsules: One-two capsules once daily.
Hi Dee® 5000 I.U. Capsules: One capsule once daily or one capsule every other day.
Hi Dee® 10.000 I.U. Capsules: One capsule every other day.
Hi Dee® 50.000 I.U. Capsules: One capsule once weekly for two-three months.

If you take more Hi Dee® than you should
If you accidentally take several capsules too many, tell your doctor or get other medical advice immediately. If possible, take the capsules, the box and this leaflet with you to show to the doctor. If you take too many capsules, you may feel or be sick, become constipated or have stomach pains, weak muscles, tiredness, lack of appetite, kidney problems and in severe cases irregular heartbeats. Excessive intake of vitamin D leads to the development of hyperphosphatemia or hypercalcemia. Associated effects with hypercalcemia include hypercalciuria, 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.
Symptoms of overdosage include anorexia, lassitude, nausea and vomiting, constipation or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo. Infants and children are generally more susceptible to its toxic effects. 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 Hi Dee® capsules
If you forget to take your capsules, take them as soon as you can. After that, take the next capsule in accordance with the instructions given to you by your doctor. Do not take a double dose 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, this medicine can cause side effects, although not everybody gets them.
Stop taking Hi Dee® and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:
o swollen face, lips, tongue or throat
o difficulty to swallow
o hives and difficulty breathing.

Side effects with Cholecalciferol may include:
Uncommon (may affect up to 1 in 100 people)
• too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion;
• too much calcium in your urine (hypercalciuria).
Rare (may affect up to 1 in 1,000 people)
• skin rash;
• itching;
• hives.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hi Dee®

• Keep out of the sight and reach of children.
• Capsules: Store below 25°C, protect from light.
• Drops: Store in cold place at 2 - 8°C.
• Do not use **Hi Dee®** after the expiry date which is stated on the pack after "EXP". The expiry date refers to the last day of that month.
• Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Further information

What Hi Dee® contains
The active substance is Vitamin D3 (Cholecalciferol).
Hi Dee® 2,000 IU Capsules: Each soft gelatin capsule contains 2000 IU equivalent to 50 µg Vitamin D3 (Cholecalciferol).
Hi Dee® 5,000 IU Capsules: Each soft gelatin capsule contains 5,000 IU equivalent to 0.125 mg Vitamin D3 (Cholecalciferol).
Hi Dee® 10,000 IU Capsules: Each soft gelatin capsule contains 10,000 IU equivalent to 0.250 mg Vitamin D3 (Cholecalciferol).
Hi Dee® 50,000 IU Capsules: Each soft gelatin capsule contains 50,000 IU equivalent to 1.25 mg Vitamin D3 (Cholecalciferol).
Also, Hi Dee® is available as oral drops:
Hi Dee® 2,000 IU Drops: Each 5 drops (about 0.17ml) of the oral solution contains 2000 IU equivalent to 50 µg Vitamin D3 (Cholecalciferol) filled in 10 ml bottle.
The other ingredients are: Arachis oil, butylhydroxyanisole (BHA), gelatin, and glycerin.
FD & blue number 1 in **Hi Dee®** 2,000 IU & 50,000 IU, Ariavit Quinoline Yellow in **Hi Dee®** 5,000 IU, & Red number 33 in **Hi Dee®** 10,000 IU.

What Hi Dee® looks like and contents of the pack
Hi Dee® 2,000 IU Capsules: Greenish blue oval soft gelatin capsules contain pale yellowish oily liquid.
Hi Dee® 5,000 IU Capsules: Yellow oval soft gelatin capsules contain pale yellowish oily liquid.
Hi Dee® 10,000 IU Capsules: Pinkish red oval soft gelatin capsules contain pale yellowish oily liquid.
Hi Dee® 50,000 IU Capsules: Blue oval soft gelatin capsules contain pale yellowish oily liquid.
Hi Dee® 2,000 IU, 5,000 IU, and 10,000 IU capsules are available in HDPE jars of 30 Soft gelatin capsules.
Hi Dee® 50,000 IU capsules are available in HDPE jars of 8, 12 & 20 soft gelatin capsules. Not all pack sizes may be marketed.

Manufacturer & Marketing Authorisation Holder
The United Pharmaceutical Manufacturing Co. Ltd.
P.O. Box 69 Amman 11591, Jordan

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For any information about this medicinal product, please contact the local representative of the Marketing Authorization Holder:
Number: +962 6 5823618
Website: www.mspharma.com
Email: pharmacovigilance@mspharma.com

To report any side effect(s):
Jordan Food & Drug Administration:
• Email: jpc@jfda.jo
• Website: https://primaryreporting.who-umc.org/jo
• Phone No: +962-6-5632000
• QR code:

This is a medicament:
• 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

Manufacturer & Marketing Authorisation Holder
The United Pharmaceutical Manufacturing Co. Ltd.
P.O. Box 69 Amman 11591, Jordan

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