



Vitamin D<sub>3</sub> 1000 IU

DIETARY SUPPLEMENT

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

Always take this supplement exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects NOT listed in this leaflet. See section 4.

#### What is in this leaflet:

- What Nano-D<sup>®</sup> capsule is and what it is used for?
- What you need to know before you take Nano-D<sup>®</sup> capsule.
- How to take Nano-D<sup>®</sup> capsule?
- Possible side effects.
- How to store Nano-D<sup>®</sup> capsule?
- Contents of the pack and other information.

#### 1. What Nano-D<sup>®</sup> capsule is and what it is used for

Nano-D<sup>®</sup> capsule contains 1000 IU vitamin D<sub>3</sub> (equivalent to 0.025 mg vitamin D<sub>3</sub>) for the regulation of the absorption and metabolism of calcium and for the integration of calcium into bone tissue.

Vitamin D is important for the absorption of calcium from the stomach and for the functioning of calcium in the body. Furthermore, it is used to treat or prevent many conditions caused by a lack of vitamin D, especially conditions of the skin or bones.

Vitamin D may also be used for purposes not listed in this medication guide.

Nano-D<sup>®</sup> capsule are specifically designed for:

- Prophylaxis of vitamin D deficiency in children and adults with an identified risk;
- Correction of vitamin D levels in osteoporosis (thinning of bone tissue) in adults.

#### 2. What you need to know before you take Nano-D<sup>®</sup> capsule

Do not take Nano-D<sup>®</sup> capsule:

- If you are allergic to vitamin D<sub>3</sub> or any of the other ingredients of this supplement (listed in section 6).
- If you suffer from hypercalcaemia (high calcium levels in the blood).
- If you have hypercalciuria (high calcium levels in the urine).
- If you have been diagnosed with hypervitaminosis D (high vitamin D levels in the blood).
- If you have kidney stones.

Ask your doctor or your pharmacists for further information.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Nano-D<sup>®</sup> capsule. Use with caution if:

- You have a tendency to get calcium-containing kidney stones.
  - You have problems in calcium and phosphate excretion through your kidneys.
  - You are being treated with medicines to increase urine output (benzothiadiazine derivatives).
  - Your mobility is greatly restricted, as there is a risk in this case of hypercalcaemia (high calcium levels in the blood) and hypercalciuria (high calcium levels in the urine).
  - You have sarcoidosis (a specific disease that affects the connective tissue of the lungs, skin and joints), as there is a risk of increased conversion of vitamin D into its active form. In such cases, blood and urine calcium levels should be monitored by the doctor.
  - You have parathyroid hormone imbalance (pseudohypoparathyroidism), as vitamin D requirements may be reduced by the sometimes normal sensitivity to vitamin D. In this case, there is a risk of long-term overdose. For such patients, more manageable active substances with vitamin D activity are available.
  - You have heart disease.
  - You have electrolyte imbalance.
  - Your kidneys are not working properly and you are using with Nano-D<sup>®</sup> capsule, the effect of treatment on the calcium and phosphate balance should be monitored by your doctor.
- If other medicines containing vitamin D are prescribed (e.g. most of the Calcium supplements), the vitamin D dose consumed when using Nano-D<sup>®</sup> capsule must be taken into account.

#### Other medicines and Nano-D<sup>®</sup> capsule

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Nano-D<sup>®</sup> capsule can be affected by the simultaneous use of:

- Phenytoin (medicine used to treat epilepsy) or barbiturates (medicines used to treat epilepsy and sleep disorders and for anesthesia);
- Glucocorticoids (medicines used to treat certain allergic conditions);
- Rifampicin and Isoniazid (medicines used to treat tuberculosis);
- Cholestyramine (medicine used to lower high cholesterol levels), laxatives containing liquid paraffin;
- Actinomycin (medicine used to treat cancer);
- Imidazole (antifungal agent);
- Orlistat (medicine used to treat adiposity, over weight and obesity).

The side effects of Nano-D<sup>®</sup> capsule can be increased by the simultaneous use of:

- Vitamin D metabolites or analogues (e.g. calcitriol);
- Combination with Nano-D<sup>®</sup> capsule is recommended only in exceptional cases under strict medical supervision.
- Medicines for increasing urine output (thiazide diuretics):
- A reduction in the elimination of calcium via the kidneys can cause calcium concentrations in the blood to rise (hypercalcaemia). Calcium levels in the blood and urine should therefore be monitored during long-term usage.

When taken at the same time, Nano-D<sup>®</sup> capsule can increase the risk of side effects of:

- Cardiac glycosides (e.g. digoxin; medicines used to increase the functioning of the heart muscles);

The risk of heart rhythm disturbances can increase as a result of a rise in calcium levels in the blood during use of vitamin D. In such cases, the doctor in charge should carry out ECG monitoring as well as monitoring of calcium levels in the blood and urine and of levels of the medicine in the blood.

#### Nano-D<sup>®</sup> capsule with food and drink

Nano-D<sup>®</sup> capsule should be taken together with food and drink.

If you have sugar intolerance, contact your doctor before taking this product.

#### 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 supplement.

#### Driving and using machines

Nano-D<sup>®</sup> capsule is not known to have any effect on driving or using machines.

#### 3. How to take Nano-D<sup>®</sup> capsule

Always take this supplement exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

##### The recommended dose is:

One Nano-D<sup>®</sup> capsule daily (equivalent to 0.025 mg or 1000 IU of vitamin D<sub>3</sub>). The doctor in charge shall decide on the dose. For patients who cannot swallow the capsule (due to aging or swallowing disorders), please ask your doctor about possibility of dissolving the ingredient of capsule within a drink or food.

##### Use in infants and toddlers

Use of Nano-D<sup>®</sup> in infants or toddlers must be under supervision of a qualified physician.

##### If you take more Nano-D<sup>®</sup> capsule than you should

The signs of an overdose are not very characteristic, manifesting as nausea, vomiting, initial diarrhea progressing to constipation, loss of appetite, lassitude, headache, painful muscles and joints, arrhythmia (irregular heartbeat), azotemia (high nitrogen levels in the blood), increased thirst, increased urinary urge and at the final stage dehydration. Please ask your doctor about the signs of a vitamin D overdose. There is no specific antidote.

Your doctor will then initiate the necessary countermeasures.

##### If you forget to take Nano-D<sup>®</sup> capsule

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra dose to make up the missed dose. Do not take a double dose to make up for a forgotten dose.

##### If you stop taking Nano-D<sup>®</sup> capsule

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

#### 4. Possible side effects

Like all supplements, this product can cause side effects, although not everybody gets them.

The frequencies of side effects are not known, as no major clinical studies allowing any estimation of frequencies have been conducted.

You should stop taking Nano-D<sup>®</sup> capsule and immediately contact your doctor if any of the following signs of a severe allergic reaction appear:

- Thinking problems, changes in behavior and feeling irritable;

- Urinating more than usual;
- Chest pain and feeling shortness of breath;
- Early signs of vitamin D overdose (weakness, metallic taste in your mouth, weight loss, muscle or bone pain, constipation, nausea and vomiting);
- Swollen face and swollen lips, tongue or throat;
- Swallowing difficulties;
- Hives and labored breathing.

#### The following side effects can occur:

- Hypercalcaemia (high calcium levels in the blood) and hypercalciuria (high calcium levels in the urine);
- Gastrointestinal complaints such as constipation, flatulence, nausea, abdominal pain or diarrhea;
- Hypersensitivity reactions such as itching, skin rash or nettle rash.

#### 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 by ~~visiting our website~~ you can help provide more information on the safety of this supplement.

24 hours patient support: +98 (21) 42593

#### 5. How to store Nano-D<sup>®</sup> capsule

Keep this supplement out of the sight and reach of children. Do not use this product after the expiry date which is stated on bottle and the carton after "Exp. Date." The expiry date refers to the last day of that month.

#### Storage conditions

Store at temperature between 15-30 °C away from moisture, light and heat.

Do not store above 30°C.

Keep the bottle in the outer carton in order to protect from light. 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 protect the environment.

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

##### What Nano-D<sup>®</sup> capsule contains

- Serving size: 1 capsule.
- The active ingredient per serving dose is:

| Amount Per Serving             | %Daily Value |
|--------------------------------|--------------|
| Vitamin D <sub>3</sub> 1000 IU | 250          |

- The other ingredients are: Lactose monohydrate, Microcrystalline cellulose, Colloidal silicon dioxide, Magnesium stearate, Croscarmellose sodium.

##### What Nano-D<sup>®</sup> capsule look like and contents of the pack

The capsules have clear transparent body and transparent orange cap. Nano-D<sup>®</sup> capsule is available in bottles containing 60 capsules.

Manufacturer and Marketing Authorization Holder:

Nano Hayat Darou Ltd.  
No. 168/2, 16th Noavari Street, Pardis Technology Park, Pardis, Tehran, Iran.

Disclaimer: Hereby, Nano Hayat Darou Ltd.

confirms that during manufacturing of this product, Nanoparticles or Nanotechnology has not been used in any ways. The "Nano" word in the name of the product only refers to name of the company, Nano Hayat Darou, and have no other purposes.



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