Package leaflet: Information for the patient

Dnord 255 microgram soft capsules
calcifediol

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Dnord is and what it is used for

It contains a form of vitamin D, calcifediol, which is used to treat vitamin D deficiency and derived problems. Vitamin D is involved in the human body, among other actions, it increases the calcium absorption.

Dnord is used to treat vitamin D deficiency in adults and to prevent vitamin D deficiency in adults with identified risks such as in patients with malabsorption syndrome, chronic kidney disease mineral and bone disorder (CKD-MBD) or other identified risks.

Dnord is also used to treat thinning of the bone (osteoporosis), as supplement of other medicines in patients with vitamin D deficiency or at risk of vitamin D deficiency.

2. What you need to know before you take Dnord

Do not take Dnord:
- If you are allergic to calcifediol or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from hypercalcaemia (high levels of calcium in the blood) or hypercalciuria (high levels of calcium in the urine).
- If you suffer from calcium stones formation.
- If you have been diagnosed with hypervitaminosis D (excess of vitamin D in the organism).

Warnings and precautions
Talk to your doctor or pharmacists before taking Dnord.
- You should not exceed the recommended daily intake of vitamin D supplements, like this medicine, because it may result in poisoning (see section 3, paragraph *If you take more Dnord than you should).*
- While you are taking this medicine or before you start, your doctor may tell you to take blood or urine tests to check levels of calcium, phosphorus and other parameters.

- Patients with kidney disease require special care and must be specially monitored by the doctor, conducting regular analysis.
- Patients with heart disease require special care and must be frequently monitored by the doctor to control blood calcium, especially those receiving treatment with cardiac glycosides (see in this section, paragraph *Taking Dnord with other drugs*).
- If you have hypoparathyroidism (insufficient function of the parathyroid hormone) this drug may be less active.
- If you have a tendency to get calcium-containing kidney stones, your doctor should monitor your blood calcium levels.
- Patients with prolonged immobilization may need lower doses of this medication.
- Patients with sarcoidosis (disease with nodules, usually on the skin), tuberculosis or other diseases with nodules should be especially careful with this medication, as they have more risk of side effects at lower doses than the recommended ones. Periodic analyses should be performed to control the levels of calcium in blood and urine.
- Interference with laboratory tests: If you are going to have any diagnostic test done (including blood, urine, skin tests using allergen, etc.) inform the doctor that you are taking this medication because it may influence the results. For example, in a cholesterol test.

Children and adolescents
The efficacy and safety of Dnord in children and adolescents below the age of 18 years have not yet been established. No data are available.

Other medicines and Dnord

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

Some medicines can alter the way this medicine works. On the other hand, Dnord or its active ingredient calcifediol can affect the effectiveness of other drugs taken simultaneously.

Therefore, they may interact with the following drugs:
- Medicines used to treat epilepsy (such as phenytoin, phenobarbital and primidone) and other enzyme-inducing drugs (favouring the reduction of Dnord effect).
- Heart medicines and/or hypertension and cardiac glycosides, thiazide diuretics or verapamil.
- Cholestyramine, colestipol (for cholesterol), orlistat (for obesity). Intake of these drugs and calcifediol should be separated at least 2 hours.
- Mineral oil or paraffin (laxatives): Using another type of laxative or separating intake of both drugs is recommended.
- Some antibiotics (such as penicillin, neomycin and chloramphenicol).
- Magnesium salts.
- Other products with Vitamin D.
- Calcium supplements.
- Corticosteroids (anti-inflammatory drugs).

Dnord with food and drinks
Some foods and drinks are supplemented with vitamin D. This should be taken into account since the effects could be added to the effects of this medicine and therefore be excessive.

Pregnancy, breast-feeding and fertility
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.

Do not take this medicine during pregnancy.

Do not take this medicine while breastfeeding your baby.

Driving and using machines
Dnord has no or negligible influence on the ability to drive and use machines.

Dnord contains ethanol, sorbitol (E-420) and sunset yellow (E-110).

This medicine contains 5 mg of alcohol (ethanol) in each soft capsule. The amount in one capsule of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
This medicine contains 22 mg of sorbitol in each soft capsule, which is equivalent to 0.03 mg/mg.
This medicine contains sunset yellow (E-110) which may cause allergic reactions.

3. How to take Dnord

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

Do not take more medicine or more often than what has been prescribed (weekly, biweekly or monthly). If you do, the risk of overdose increases.

Recommended doses are as follows:

Treatment of vitamin D deficiency and prevention of vitamin D deficiency in patients with identified risks: one capsule once a month.

Addition to specific therapy for osteoporosis: one capsule once a month.

There are populations at high risk of vitamin D deficiency which may need to take higher doses, after analytical verification of the extent of the deficiency, the doctor may consider a dose of one capsule every two weeks or every week. This medicine should not be administered with a daily frequency.

Your doctor should monitor your calcium and vitamin D levels periodically, usually before starting the treatment and after 3-4 months. Depending on the indication, doses will be generally reduced or spaced in time when symptoms improve, or vitamin D deficiency has been overcome.

For oral use

If you feel that the effect of this medicine is too strong or too weak, please contact your doctor or pharmacist.

If you take more Dnord than you should

If you take more of this medicine than the dose prescribed by your doctor (overdose) and/or for a long time, hypercalcemia (high blood calcium levels) and phosphates in urine and blood may appear, possibly leading to kidney failure. Some symptoms of toxicity can appear early and others later on. Initial symptoms include: weakness, fatigue, headache, loss of appetite, dry mouth, digestive disorders such as vomiting, abdominal cramps, constipation or diarrhoea, increased thirst; increased urination, muscle pain. Some symptoms that may occur later are: itching, weight loss, stunted growth in children, kidney disorders, intolerance to sunlight, conjunctivitis, increased cholesterol, transaminases, inflammation of the pancreas, calcification (calcium salts deposits) in blood vessels and other tissues such as tendons and muscles, increased blood pressure, mental disorders, irregular heartbeat. The symptoms of overdose usually improve or disappear when treatment is stopped, but if intoxication is severe kidney or heart failure can occur.

If you forget to take Dnord
Do not take a double dose to make up for a forgotten capsule.
Take the missed dose as soon as possible; then back to your regular dosing schedule.

If you stop taking Dnord

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

4. Possible side effects

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

Adverse effects can occur in case of excessive or more prolonged treatment than prescribed by your doctor, which may cause hypercalcemia (increased levels of calcium in blood), and hypercalciuria (increased calcium levels in urine), see section 3 for description of symptoms.

Other adverse effects include allergic reactions such itching, local swelling, difficulty in breathing and skin redness.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dnord

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 further information

What Dnord contains

- The active substance is calcifediol. Each soft capsule contains 255 micrograms of calcifediol as calcifediol monohydrate.

- The other ingredients are: anhydrous ethanol, medium chain triglycerides and the components of the capsule include: gelatin, glycerol, sorbitol (E-420), titanium dioxide (E171) and sunset yellow (E-110).

What Dnord looks like and content of the pack

Dnord are orange, oval soft gelatine capsules containing a clear, low viscous liquid free from particles packed in PVC / PVDC-Alu blisters containing 1, 2, 3, 5 or 10 capsules. Blisters are packed in a cardboard box.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Nordic Pharma Limited
4045 Kingswood Road,
Dublin 24
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Manufacturer
Faes Farma, S.A.
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria: Hidroferol 266 mikrogramm weichkapsel
Czechia: Uperold
France: Luzadel 266 microgrammes capsule molle
Hungary: Defevix 266 mikrogramm lágy kapszula
Ireland: Dnord 255 microgram soft capsules
Norway: Hidrosun
Portugal: Hidroferol 266 microgramas cápsula mole
Slovenia: Defevix 266 mikrogramov mehke kapsule
Spain: Hidroferol 0,266 mg cápsulas blandas
Sweden: Hidrosun 255 mikrogram kapsel, mjuk
Slovakia: Defevix 266 mikrogramov mäkká kapsula
Croatia: Defevix 266 mikrograma meke kapsule
Greece: Hidroferol 266 μικρογραμμάρια καψάκιο, μαλακό

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