

Package leaflet: Information for the user

NAT D

(Vitamin D3 125µg5000 IU soft gelatin capsule)

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. See section d below.

What is in this leaflet

- a) What NAT D is and what it is used for
- b) What you need to know before you take NAT D
- c) How to take NAT D
- d) Possible side effects
- e) How to store NAT D
- f) Further information

a) What NAT D is and what it is used for

NAT D, Oral Softgel Capsule is a vitamin product containing cholecalciferol 125 µg (equivalent to vitamin D3...5000IU). Vitamin D can be found in some foods and also produced by the body when skin is exposed to sunlight. Vitamin D helps the kidneys and intestine absorb calcium and it helps build bones.

NAT D, Oral Softgel Capsule is used:

- For prevention of vitamin D deficiency when there is significant risk of deficiency or/and increased demand for vitamin D
- With other medicines to treat certain bone conditions, such as thinning of the bone(osteoporosis), particularly in frail adults who are at higher risk of falls, injuries and fractures.
- To treat vitamin D deficiency that has been confirmed by laboratory tests.

b) What you need to know before you take NAT D

Do not take NAT D if:

- You are allergic to vitamin D or any other ingredients of NAT D (refer to section Product description {what Nat D contains}: Ingredients below)
 - You have hypercalcaemia (high levels of calcium in the blood)
 - You have hypercalciuria (high levels of calcium in the urine)
 - You have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism)
 - You have renal calculi (kidney stones)
 - You have hypervitaminosis D (high levels of vitamin D in the blood).
- Do not take NAT D if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking NAT D.

Take special care with NAT D

Before you take NAT D you should tell your doctor if you:

- Are undergoing treatment with certain medicines used to treat heart disorders (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 NAT D
- Taking 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 NAT D

- Have kidney damage or disease.

Your doctor may want to measure the levels of calcium in your blood or urine

Children and adolescents

As directed by a physician

Taking NAT D with Other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines especially the following:

- Thiazide diuretics reduce the urinary excretion of calcium. Due to the increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
- Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D since the metabolism increases.
- Excessive dosing of vitamin D can induce hypercalcaemia, which may increase the risk of digitalis toxicity and serious arrhythmias due to the additive inotropic effects. The electrocardiogram (ECG) and serum calcium levels of patients should be closely monitored.
- Glucocorticoid steroids may increase vitamin D metabolism and elimination. During concomitant use, it may be necessary to increase the dose.
- Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D. Orlistat may potentially impair the absorption of cholecalciferol as it is fat-soluble.
- The cytotoxic agent actinomycin and imidazole antifungal agents interfere with vitamin D activity by inhibiting the conversion of 25-hydroxyvitamin D to 1,25-dihydroxyvitamin D by the kidney enzyme, 25-hydroxyvitamin D-1-hydroxylase.

Pregnancy, breast-feeding and fertility

Pregnancy

Vitamin D should be used during pregnancy, only in the case of a vitamin D deficiency.

Vitamin D is not recommended during pregnancy in patients without a vitamin D deficiency as the daily intake should not exceed 600 IU vitamin D.

There are no indications that vitamin D at therapeutic doses is teratogenic in humans

Breast-feeding

Vitamin-D can be used during breast-feeding. Vitamin D3 passes into breast milk. This should be considered when giving additional vitamin D to the child.

Fertility

There are no data on the effect of Vitamin-D on fertility. However, normal endogenous levels of vitamin D are not expected to have any adverse effects on fertility.

Driving and using machines

None reported

c) How to take NAT D

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

For adults (6-18years) 1 capsule daily, with meal or as directed by a physician.

For adults (over 18years) 1to 2 capsules daily, with meal or as directed by a physician for treatment of vitamin D deficiency and 1 capsule or as directed by a physician daily in Vitamin D supplementation in frail older patients

Method of administration:

Oral use

Capsules must be swallowed whole, with a sufficient quantity of liquid. They must not be broken or chewed.

If you take more NAT D than you should

In such cases please contact your doctor or pharmacist immediately even if you feel well.

If you forget to take NAT D

If you forget to take the capsule.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you stop taking NAT D

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop.

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

d) Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the side effects are temporary with continued treatment or disappeared when treatment is stopped.

Stop taking NAT D and talk to your doctor if you experience:

Symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties. Stop taking NAT D and talk to your doctor immediately.

Vitamin D administration related adverse effects, such as hypercalcemia and hypercalciuria are rare, and usually result from taking extremely high doses of vitamin D for a prolonged time.

e) How to store NAT D

Store below 30°C in a dry place, away from direct sunlight.

f) Further information

What NAT D contains

Each soft gelatin capsule contains: Vitamin D3 125µg5000 IU

Capsule Fill: Soyabean Oil and Butylated hydroxytoulene

Capsule Shell: Gelatin, Glycerin and Purified water.

What NAT D looks like and contents of the pack:

NAT D is a clear pale yellow oily liquid filled in 4 minim oval shape, transparent natural color, and soft gelatin capsule

NAT-D is available as 30s and 60s soft gelatin capsules packed in PP bottles.

Marketing Authorisation Holder:

MEGA LIFESCIENCES Public Company Limited

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