SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

NAT D

1.1 Strength

Vitamin D3 125µg ……5000IU

1.2 Pharmaceutical form

Soft gelatin capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft gelatin capsule contains: Vitamin D3 125µg ……5000 IU

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soft gelatin capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

NAT-D is indicated in treatment of Vitamin D deficiency. To supplement vitamin D in older adults with vitamin D deficiency, particularly in frail adults who are at higher risk of falls, injuries and fractures.

4.2 Posology and method of administration

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

4.3 Method of administration

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

4.4 Contraindications

- Hypersensitivity or intolerance to any component of the product.

4.5 Special warnings and precautions for use

None

4.6 Paediatric population

As directed by a physician

4.7 Interaction with other medicinal products and other forms of interaction

- 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 arrhythimias 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.

4.8 Additional information on special populations

None

4.9 Paediatric population

None

4.10 Fertility, pregnancy and lactation

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.

4.11 Effects on ability to drive and use machines

None reported

4.12 Undesirable effects

Adverse reactions frequencies as defined as: uncommon (≥1/1,00 < 1/100), rare (≥ 1/10,000,< 1/100) or not known (cannot be estimated from the available data).

Immune system disorders

Not known (cannot be estimated from the available data): Hypersensitivity reactions such as angio-oedema or laryngeal oedema.

Metabolism and nutrition disorders

Uncommon: Hypercalcaemia and hypercalciuria.

Skin and subcutaneous disorders

Rare: Pruritus, rash and urticaria.

4.13 Overdose

Overdose can lead to hyper-vitaminosis D. An excess of vitamin D causes abnormally high levels of calcium in the blood, which can eventually severely damage the soft tissues, and kidneys. Tolerable Upper Intake Level for vitamin D3 (cholecalciferol) is set at 4000 IU (100 µg) per day. Vitamin D3 should not be confused with its active metabolites. Cholecalciferol

Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, renal calculi and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death.

Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification. Treatment of hypercalcaemia: The treatment with vitamin D must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, and cardiac glycosides must also be discontinued. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vitamin D and analogues, colecalciferol ATC Code: A11CC05

Vitamin D increases the intestinal absorption of calcium and phosphate.

Administration of vitamin D3 counteracts development of rickets in children and osteomalacia in adults. It also counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which causes increased bone resorption. In addition to bone and intestinal mucosa many other tissues have vitamin D receptors, to which the active hormonal form of vitamin D, calcitriol, binds.

5.2 Pharmacokinetic properties

Absorption

Vitamin D is easily absorbed in the small intestine.

Distribution and biotransformation

Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Cholecalciferol is converted in the liver by hydroxylation to 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25-dihydroxycholecalciferol. 1,25-dihydroxycholecalciferol is the active metabolite responsible for increasing calcium absorption. Vitamin D, which is not metabolised, is stored in adipose and muscle tissues.

After a single oral dose of cholecalciferol, the maximum serum concentrations of the primary storage form are reached after approximately 7 days. 25(OH) D3 is then slowly eliminated with an apparent half-life in serum of about 50 days. Cholecalciferol and its metabolites are excreted mainly in the bile and faeces.

Elimination

Vitamin D is excreted mainly in bile and faeces with a small percentage found in urine

5.3 Preclinical safety data

At doses far higher than the human therapeutic range teratogenicity has been observed in animal studies. There is further no information of relevance to the safety assessment in addition to what is stated in other parts of the SmPC

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule Fill: Soyabean Oil and Butylated hydroxytoulene

Capsule Shell: Gelatin, Glycerin and Purified water.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container
NAT-D is available as 30 and 60 soft gelatin capsules packed in PP bottles

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

MEGA LIFESCIENCES Public Company Limited
384 Moo 4, Soi 6, Bangpoo Industrial Estate,
Pattana 3 Road, Phraeksa, Mueang,
Samutprakarn 10280, Thailand.

8. MARKETING AUTHORISATION NUMBER: N/A

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION: N/A

10. DATE OF REVISION OF THE TEXT

27 March 2023