For the use of a Registered Medical Practitioner only

1.0 GENERIC NAME AND BRAND NAME

Vitamin D3 Oral Solution 60000 IU
arachitol® NANO 60k IU

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Cholecalciferol I.P. 60000 IU
(In Nano Droplet form)
In a flavoured sugar free base
Excipients q.s.
Colour: Tartrazine Supra
Appropriate overages of Vitamin added

3.0 DOSAGE FORM & STRENGTH

Oral solution 60000 IU

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prevention & treatment of Vitamin D deficiency states

4.2 Posology and Method of Administration

Vitamin D3 60000 IU to be given once a week for a period of 8 weeks, followed by maintenance daily dose as directed by the physician.
It is advisable to check serum 25(OH) D level after 4 week of initiation of therapy for dose adjustment if necessary.
Pediatric use – As prescribed by the physician

4.3 Contraindications

- Hypersensitivity to cholecalciferol, ergocalciferol, or Vitamin D metabolites (eg calcitriol, calcifediol, alfacalcidol, calcipotriol).
- Hypercalcemia (exacerbation with enhanced toxicity)

4.4 Special Warnings and Precautions for Use

Vitamin D should be used with caution in patients with impairment of renal function and the effects on calcium and phosphate levels should be monitored, the risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, vitamin D in the form of cholecalciferol is not metabolized normally and other forms of vitamin D should be used. Caution is required in patients suffering from cardiac conditions like arteriosclerosis due to the possible exacerbation related to hypercalcaemia and in patients with hyperlipidemia due to possibility of LDL elevation. Vitamin D should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of vitamin D to its active form. These patients should be monitored with regard to the calcium content in serum and urine. Medical supervision is required whilst on treatment to prevent hypercalcaemia.

4.5 Drugs Interactions

Calcipotriene is a drug that is similar to vitamin D. taking vitamin D along with calcipotriene might increase the effects and side effects of calcipotriene. Taking vitamin D along with digoxin might increase the effects of digoxin and lead to an irregular heartbeat.

Taking large amount of vitamin D along with diltiazem might decrease the effectiveness of diltiazem. When given along with antacids, vitamin D increases the absorption of aluminum salts.

4.6 Use in Special Populations

Pregnancy:

There is lack of data regarding the use of high doses of Vitamin D in pregnancy.

Available evidence is inconclusive or is inadequate for determining fetal risk when used in pregnant women or women of childbearing potential. Recommended to weigh the potential benefits of the treatment against potential risks.

The administration of vitamin D should be under strict supervision of the physician.

Lactation:

Infant risk cannot be ruled out when administered in high doses during lactation. Administration of vitamin D during lactation should be under the supervision of the treating physician.

Hepatic insufficiency:

The intestinal absorption of cholecalciferol may be markedly impaired; conversion to calcifediol may also be reduced significantly, with the requirement of high doses. Agents not requiring hepatic hydroxylation (e.g. calcitriol, alphacalcidol) are preferred.

Renal Insufficiency:

Although only small amounts of a vitamin D dose are recovered in the urine, metabolic conversion to calcitriol is impaired and higher doses are generally required in most conditions. Agents not requiring renal hydroxylation (e.g. calcitriol) are preferred.

4.7 Effects on Ability to Drive and Use Machines

There are no data about the effect of this product on driving capacity. An effect is, however, unlikely

4.8 Undesirable Effects

High dose of cholecalciferol can cause weakness, fatigue, sleepiness, headache, loss of appetite, dry mouth, metallic taste, nausea and vomiting. Vitamin D toxicity, including nephrocalcinosis /renal failure, hypertension, can occur with prolonged use of cholecalciferol, relatively low doses can produce toxicity in hypersensitive infants and children. Hypervitaminosis D is reversible upon discontinuation of treatment unless renal damage is severe.

4.9 Overdose

Although no long-term studies have examined higher doses of vitamin D on serum calcium levels, there are no reported cases of vitamin D intoxication to suggest that intakes of up to 4000 IU/d of vitamin D cause hypercalcemia. In healthy adults, 5 months of ingesting 10,000 IU/d of vitamin D neither caused hypercalcemia nor increased urinary calcium excretion, which is the most sensitive indicator for potential vitamin intoxication.

In case of toxicity Immediate cessation of vitamin D intake is indicated, with a low-calcium diet, glucocorticoid administration, and fluid support. Vitamin D intoxication is usually reversible with these measures; gradual falls in serum calcium and mobilization of calcium from soft tissue occur. Recovery of renal function is seen unless renal damage was severe prior to treatment

Vitamin D toxicity associated with hypercalcemia is a well-recognized complication of acute or long-term administration of cholecalciferol. Hypercalcemia is solely related to circulating levels of calcifediol. Initial symptoms related to hypercalcemia include diarrhea, constipation (primarily in children/adolescents), nausea, vomiting, anorexia, polyuria, polydipsia, nocturia, weakness/fatigue, headache and mental changes.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Vitamin D is hydroxylated in the liver to form 25- hydroxycholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1,25 dihydroxycholecalciferol (calcitriol) . In its biologically active form vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroid is inhibited directly by the biologically active form of vitaminD3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D3.

5.2 Pharmacodynamic Properties

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.

5.3 Pharmacokinetic Properties

Absorption

Vitamin D is easily absorbed in the small intestine.

Distribution and metabolism

Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Cholecalciferol is converted in the liver by hydroxylation to 25-hydroxycolecalciferol. 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.

Elimination

Vitamin D is excreted in faeces and urine.

6.0 NONCLINICAL PROPERTIES

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

7.DESCRIPTION
Clear, transparent flavoured syrupy liquid

8.PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities
Not Applicable

8.2 Shelf-Life
Refer Pack

8.3 Packaging Information
5 ml

8.4 Storage and Handing Instructions
Store at a temperature not exceeding 25°C. Protect from direct sunlight.

9.0 Patient Counselling Information
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 healthcare provider.
- 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 4.

1. What Arachitol Nano® is and what it is used for?
Arachitol Nano® contains vitamin D3 which is essential for healthy bones. Vitamin D3 belongs to a group of medicines called vitamin supplements which are used to correct and maintain levels of the vitamin in your body.
Vitamin D is produced naturally by your skin after exposure to the sun and is also found in some foods. When levels of vitamin D in the body are too low this can cause bones to become fragile.
Arachitol Nano® is used to prevent and treat: very low levels of vitamin D (deficiency)
Arachitol Nano® can also be used in combination with other medicines to treat certain bone conditions such as thinning of the bones (osteoporosis).

2. What you need to know before you take Arachitol Nano®:

Do not take Arachitol Nano®:

- if you are allergic to vitamin D or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have kidney stones or serious kidney problems
- if you have high levels of calcium in your blood (hypercalcaemia)
- if you have high levels of calcium in your urine (hypercalciuria)

Warnings and precautions
Talk to your doctor or pharmacist before taking Arachitol Nano®:

- if you have problems with your kidneys
- if you have sarcoidosis (inflammation that produces lumps of cells in various organs in the body).

Your doctor will be able to tell you if you are already taking other medicines or supplements containing vitamin D
Your doctor may wish to do blood or urine tests to monitor your treatment.
You can take this medicine with or without food and drink.

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 healthcare provider for advice before taking this medicine.

3. How to take Arachitol Nano®?
Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
Dose for treatment of Vitamin D deficiency:
The dose needed to treat vitamin D deficiency will depend on how low your vitamin D levels are. Your doctor will advise you on the frequency of administration, which may be spread over several weeks.
After this you may need to take regular doses to maintain your vitamin D levels.

4. Possible side effects?
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Serious side effects:
Allergic reaction. The likelihood of this side effect happening to you is not known, however, stop taking Arachitol Nano® and seek immediate medical help if you have any signs of serious allergic reaction such as a swollen face, lips, tongue or throat, difficulty swallowing or breathing
Hypercalcaemia (too much calcium in your blood). This is an uncommon side effect of Arachitol Nano® which can cause nausea, vomiting, excessive passing of urine, loss of appetite, weakness, apathy, thirst, constipation, drowsiness or dizziness. Stop taking Arachitol Nano® and seek immediate medical help if these symptoms occur. Your doctor should monitor your blood calcium level during long-term treatment with Arachitol Nano®.
Other side effects: Uncommon (may affect up to 1 in 100 people)
hypercalciuria (too much calcium in your urine) which can cause increased frequency of urination, pain on urination, abdominal pain, bladder or kidney stones and urinary tract infections
Rare (may affect up to 1 in 1,000 people): itching, skin rash

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Replaces Version 1.0, Dated: 05-Sep-25

Frequency not known (frequency cannot be estimated from the available data): nausea, vomiting

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly to Abbot at webmasterindia@abbott.com.

5. How to store Arachitol Nano®?
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 blister strip or bottle after EXP. The expiry date refers to the last day of that month.
Store at a temperature not exceeding 25°C. Protect from direct sunlight.

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

10.DETAILS OF MANUFACTURER
MANUFACTURED BY:
Pulse Pharmaceuticals Pvt Ltd
At: Abbott Healthcare Pvt. Ltd.
Village Bhatauli Khurd, Baddi-173205,
Distt. Solan, Himachal Pradesh, India.

MARKETED BY:
Abbott India Limited
Angel Space, Lifestyle, Bldg. No D-4, Gala No 4 to 10,
14 to 20 Ground Floor, 107 to 110 & 117 to 120 1st Floor,
207 to 210 & 217 to 220 2nd Floor, Pimplas, Dist. Thane,
Bhiwandi - 421302, Maharashtra, India.
® - Arachitol is a Regd. Trade Mark of Abbott Healthcare Product B.V.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE
HP-MB-LL-00155 dated 25th August 2025

12. DATE OF REVISION
Version 2.0; Dated: 16-Jul-26

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com

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