

## **Package leaflet: Information for the user**

### **Vitanova-D3 Nano oral solution**

#### **Cholecalciferol (vitamin-D<sub>3</sub>)**

**Read all of this leaflet carefully before you start using 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, 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, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What VITANOVA- D3 Nano oral solution is and what it is used for
2. What you need to know before you use VITANOVA- D3 Nano oral solution
3. How to use VITANOVA- D3 Nano oral solution
4. Possible side effects
5. How to store VITANOVA-D3 Nano oral solution
6. Contents of the pack and other information

#### **1. What VITANOVA- D3 Nano oral solution is and what it is used for**

VITANOVA- D3 Nano oral solution contains the active ingredient cholecalciferol (vitamin D<sub>3</sub>). Vitamin D<sub>3</sub>, can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D<sub>3</sub> helps the kidneys and intestine absorb calcium and it helps build bones. Vitamin D<sub>3</sub> deficiency is the predominant cause of rickets (defective mineralization of bones in children) and osteomalacia (inadequate mineralization of bones in adults).

Certain populations are at high risk of vitamin D deficiency, and may require higher doses and monitoring of serum 25 (OH)D:

- Institutionalised, foster homes or hospitalised individuals
- Dark skinned individuals
- Individuals with limited effective sun exposure due to protective clothing or consistent use of sun screens
- Obese individuals
- Patients being evaluated for osteoporosis
- Use of certain concomitant medications (e.g., anticonvulsant medications, glucocorticoids)

- Patients with malabsorption, including inflammatory bowel disease and coeliac disease
- Those recently treated for vitamin D deficiency, and requiring maintenance therapy.

VITANOVA- D3 Nano oral solution is used for initial treatment of clinically relevant vitamin D deficiency in adults.

## **2. What you need to know before you use VITANOVA-D3 Nano oral solution**

### **Do not use VITANOVA-D3 Nano oral solution:**

- if you are allergic to vitamin D<sub>3</sub> or any of the other ingredients of this medicine;
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria);
- if you have kidney stones (renal calculi) or severe renal impairment;
- if you have high levels of vitamin D<sub>3</sub> in your blood (hypervitaminosis D)

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using VITANOVA-D3 Nano oral solution 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<sub>3</sub> in the body);
- are treated with diuretics (e.g. benzothiadiazine)
- are immobilized
- suffer from pseudo hypoparathyroidism
- are taking medicines containing vitamin D<sub>3</sub>, or eating foods or milk enriched with vitamin D<sub>3</sub>;
- are likely to be exposed to a lot of sunshine whilst using VITANOVA- D3;
- take 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 VITANOVA- D3;
- have kidney damage or disease and if you have a tendency for the formation of renal stones. Your doctor may want to measure the levels of calcium in your blood or urine.
- take a daily dose of vitamin D<sub>3</sub> exceeding 1,000 I.U. over a long period of time, your doctor should monitor the level of calcium in your blood by lab test.

### **Other medicines and VITANOVA- D3**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is especially important if you are taking:

- medicines that act on the heart or kidneys, such as cardiac glycosides (eg, digoxin) or diuretics (e.g., bendroflumethiazide). When used at the same time as

vitamin D<sub>3</sub> these medicines may cause a large increase in the level of calcium in the blood and urine;

- medicines containing vitamin D<sub>3</sub> or eating food rich in vitamin D<sub>3</sub>, such as, some types of vitamin D<sub>3</sub>-enriched milk;
- actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g., clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body process vitamin D<sub>3</sub>;
- medicines to treat tuberculosis e.g. rifampicin, isoniazid;
- the following medicines because they can interfere with the effect or the absorption of vitamin D<sub>3</sub>:
  - antiepileptic medicines (anticonvulsants), barbiturates;
  - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D<sub>3</sub>;
  - medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol);
  - certain medicines for weight loss that reduce the amount of fat your body absorbs (eg, orlistat);
  - certain laxatives (such as liquid paraffin).

#### **VITANOVA- D3 Nano oral solution with food, drink and alcohol**

You should take this medicine preferably together with a meal to help your body absorb the vitamin D<sub>3</sub>.

#### **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.

The product should be used during pregnancy only in case of a Vitamin D deficiency.

It is not recommended during pregnancy in patients without a Vitamin D deficiency.

#### **Driving and using machines**

VITANOVA- D3 Nano oral solution **should** not affect your ability to drive or operate machinery.

### **3. How to use VITANOVA- D3**

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

You should take Vitanova-D3 Nano oral solution preferably together with a meal.

**Adults and adolescent:** 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.

Your doctor will adjust the dose for you.

#### **Pediatric population**

Vitanova-D3 Nano oral solution 60000 I.U. should be used as prescribed by the Physician only.

### **Pregnancy and breastfeeding**

Vitanova-D3 Nano oral solution should be used during pregnancy and lactation only if the potential benefit justifies the potential risk to the mother and fetus.

If you are pregnant or think you may be pregnant or you are breast-feeding, you should talk to your doctor or pharmacist before you take Vitanova-D3 Nano oral solution.

### **If you take more VITANOVA- D3 Nano oral solution than you should**

If you take more medicine than prescribed, stop using this medicine and contact your doctor. If it is not possible to talk to a doctor go to the nearest hospital emergency department and take the medicine package with you.

The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood and in urine (hypercalcaemia and hypercalciuria) shown by lab test.

### **If you forget to take Vitanova- D3 Nano oral solution**

If you forget to take a dose of Vitanova- D3, take the forgotten dose as soon as possible. Then take the next dose at the correct time. However, if it is almost time to take the next dose, do not take the dose you have missed; just take the next dose as normal. **Do not take a double dose to make up for a forgotten dose.**

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

## **4. Possible side effects**

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

Possible side effects may include:

**Uncommon** (affects less than 1 in 100 people)

- Too much calcium in your blood (hypercalcaemia)
- Too much calcium in your urine (hypercalciuria)

**Rare** (affects less than 1 in 1000 people)

- Skin rash
- Itching
- Hives

### **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: Website: [www.zuventus.co.in](http://www.zuventus.co.in) and click the tab “Safety Reporting” located on the top of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

#### **4. How to store VITANOVA- D3**

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 pack after "Exp". The expiry date refers to the last day of that month.

Do not store above 30° C.

Store in the original package in order to protect from light.

Do not freeze.

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 to protect the environment.

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

##### **What VITANOVA- D3 contains**

The active substance is cholecalciferol (vitamin D<sub>3</sub>).

Each 5 ml syrup contains:

Cholecalciferol IP ...60000 IU

In a flavoured base q.s.

Packaging

A bottle of 5 ml

#### **7. Marketing Authorisation Holder**

Zuventus Healthcare Limited

Zuventus House, Plot Y2, CTS No.: 358/A2,

Near Nahur Railway Station,

Nahur (W), Mumbai, 400078 Maharashtra, India

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