Package leaflet: Information for the user

VITANOVA-D3 Sachets

Cholecalciferol Granules

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

1. What VITANOVA- D3 is and what it is used for

VITANOVA- D3 sachet contains the active ingredient cholecalciferol granules (vitamin D_3). Vitamin-D_3, can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D_3 helps the kidneys and intestine absorb calcium and it helps build bones. Vitamin D_3 deficiency is the predominant cause of rickets (defective mineralization of bones in children) and osteomalacia (inadequate mineralization of bones in adults). Vitamin D3 is essential for the growth, formation, and maintenance of healthy bones. Also Vitamin D also regulates many other cellular functions in your body. Its anti-inflammatory, antioxidant and neuroprotective properties support immune health, muscle function and brain cell activity.

Vitanova -D3 Sachet is a vitamin D3 supplement which is primarily used to manage and prevent vitamin D3 deficiency states in adults and children.

2. What you need to know before you use VITANOVA- D3

Do not use VITANOVA- D3:

- if you are allergic to vitamin D_3 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_3 in your blood (hypervitaminosis D)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using VITANOVA- D3 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_3 in the body);
- are treated with diuretics (e.g. benzothiadiazine)
- are immobilized
- suffer from pseudo hypoparathyroidism
- are taking medicines containing vitamin D_3, or eating foods or milk enriched with vitamin D_3;
- 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_3 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 (eg, bendroflumethiazide). When used at the same time as vitamin D_3 these medicines may cause a large increase in the level of calcium in the blood and urine;
- medicines containing vitamin D_3 or eating food rich in vitamin D_3, such as, some types of vitamin D_3-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_3;
- medicines to treat tuberculosis e.g. rifampicin, isoniazid;
- the following medicines because they can interfere with the effect or the absorption of vitamin D_3:
  - antiepileptic medicines (anticonvulsants), barbiturates;
  - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D_3;
  - 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 (e.g., orlistat);
- certain laxatives (such as liquid paraffin).

VITANOVA- D3 with food, drink and alcohol
You should take this medicine preferably together with a meal to help your body absorb the vitamin D_3.

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.
This high strength formulation is not recommended for use in pregnant and breastfeeding women.

Driving and using machines
It is not expected that Vitanova-D3 sachet would affect your ability to drive or to 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. You should take VITANOVA- D3 sachet preferably together with a meal.

Use in adults and Children

Pour the contents of the sachet into a cup of milk, stir, then drink immediately. The recommended dosage is one fourth to one sachet per day.
Your doctor or pharmacist will tell you how many sachets you need to take a day.
This initial treatment may be followed by maintenance therapy, as directed by your doctor.
Your doctor will adjust the dose for you.

If you take more VITANOVA- D3 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
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** 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.

5. 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_3).

Each sachet of 1 g contains:
Cholecalciferol IP ……. 60,000 IU
Excipients q.s.

Packaging
4 Sachet of 1g each

Marketing Authorisation Holder

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