

D₃-Vicotrat®
100.000 IU/1 ml solution for injection



Active substance: Cholecalciferol (vitamin D₃)

Read all of this leaflet carefully before administration of this medicine is started 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. 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.

What is in this leaflet

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2. What you need to know before you use D₃-Vicotrat
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1. What D₃-Vicotrat is and what it is used for

D₃-Vicotrat contains vitamin D₃ which is a hormone regulating the calcium and phosphate metabolism.

D₃-Vicotrat is used for the prophylaxis of vitamin D deficiency symptoms due to malabsorption, e.g. caused by chronic intestinal diseases, scarred alteration of the liver tissue (biliary hepatocirrhosis), extended stomach or intestines resections, if an oral therapy is impossible or ineffective.

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

Do not use D₃-Vicotrat

- if you are allergic to cholecalciferol or any of the other ingredients of this medicine (listed in section 6);
- in case of hypercalcemia (increased calcium concentration in blood) and/or
- in case of hypercalciuria (increased calcium concentration in urine);
- during pregnancy and lactation.

Warnings and precautions

Talk to your doctor or pharmacist before D₃-Vicotrat is administered.

D₃-Vicotrat should not be administered to you

- if you tend to form kidney stones containing calcium (also in the anamnesis);
- if you suffer from hereditary dysfunction of the excretion of phosphate (pseudohypoparathyroidism). The demand of vitamin D can be reduced due to the temporarily normal vitamin D sensitivity with a risk of a long-lasting overdose. In this case easily controllable vitamin D derivatives are available;

Take special care with D₃-Vicotrat,

- if your renal excretion of calcium and phosphate is impaired (in these patients the effect on the calcium and phosphate level should be monitored); if your mobility is reduced (e.g. due to a cast); if you are treated with derivatives of benzothiadiazine (drugs to increase diuresis). In these cases, there is a risk of increased calcium concentration in the blood (hypercalcemia) and increased calcium concentration in the urine (hypercalciuria). Calcium levels in blood and urine must be monitored.
- if you suffer from sarcoidosis (Boeck's disease), because the risk of transformation of vitamin D into its active metabolites is increased. The calcium levels in blood and urine should be monitored in these patients.

During long-term therapy with D₃-Vicotrat the calcium levels in blood and urine should be monitored every 3 to 6 months, and the kidney function should be checked by measuring the serum creatinine. This check is particularly important in older patients and during simultaneous therapy with cardiac glycosides (drugs to increase the contraction force of the cardiac muscle) or diuretics (drugs to increase diuresis). In case of hypercalcemia (increased calcium concentration in blood) or symptoms of impaired kidney function the dosage must be reduced or the therapy must be stopped. It is recommended to reduce the dosage or to interrupt the therapy, if the calcium level in the urine exceeds 7.5 mmol/24 hours (300 mg/24 hours).

If other drugs containing vitamin D are administered, the dosage of vitamin D from D₃-Vicotrat must be taken into account. Additional administration of vitamin D or calcium should only be carried out under a medical supervision. In such cases the calcium levels in blood and urine must be monitored.

In patients with renal impairment treated with D₃-Vicotrat, the effect on the calcium and phosphate balance should be monitored.

Other medicines and D₃-Vicotrat

Tell your doctor or pharmacist if you are taking / using, have recently taken/used or might take / use any other medicines.

D₃-Vicotrat is influenced as follows:

Phenytoin (drugs for treatment of epilepsy) or barbiturates (drugs for treatment of epilepsy and sleep disorders or for anaesthesia) can reduce the effect of Vitamin D₃.

Thiazide diuretics (drugs to increase diuresis) can lead to hypercalcemia (increased calcium concentration in blood) due to the reduction of the renal calcium excretion. Therefore, the calcium level in blood and urine should be monitored during a long-term therapy.

The simultaneous administration of glucocorticoids (drugs for treatment of certain allergic diseases) can reduce the effect of vitamin D₃.

D₃-Vicotrat influences the effects of the following drugs:

The risk of side effects during treatment with cardiac glycosides (drugs to increase the contraction force of the cardiac muscle) may be raised due to an increase of the calcium level in blood while taking vitamin D (risk of cardiac dysrhythmia). In these patients ECG and calcium level in blood and urine should be monitored.

Only in exceptional cases and under serum calcium checks D₃-Vicotrat should be combined with metabolic products or analogues of vitamin D.

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 doctor or pharmacist for advice before using this medicine.

Overdose of vitamin D in pregnancy must be prevented since long-lasting hypercalcemia (increased calcium concentration in blood) can lead to physical and mental retardation as well as to congenital heart and eye diseases of the child. Therefore D₃-Vicotrat may not be used during pregnancy and lactation.

If a vitamin D supplement should be required a drug with a lower cholecalciferol content than D₃-Vicotrat should be chosen.

Driving and using machines

No effects are known to this day.

D₃-Vicotrat contains sorbitol

Please talk to your doctor before D₃-Vicotrat is administered, if you know that you are suffering from intolerance to certain sugars.

3. How to use D₃-Vicotrat

Your doctor will give you D₃-Vicotrat directly into a muscle.

Posology

Unless otherwise prescribed by your doctor, the usual dose is:

½ - 1 ampoule (50 000 to 100 000 IU vitamin D) as a single dose in individual intervals (normal case: every 3 months).

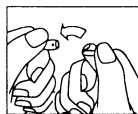
Route and method of administration

The injection solution is administered by deep intramuscular injection.

In case of an intravenous injection the oily part of the solution can lead to embolisms and the solubilizer to haemolysis depending on the applied dosage.

Duration of treatment

The treating doctor decides on the duration of treatment.



OPC ampoule

To open, turn ampoule until the point faces upwards and break off the neck with a downward movement.

Please talk to your doctor or pharmacist, if you have the impression that the effect of D₃-Vicotrat is too strong or too weak.

If you assume that more D₃-Vicotrat was applied than it should

Symptoms of overdose

Overdose leads to an increase of phosphorus in blood and urine and to the hypercalcemia syndrome (increased calcium concentration in blood), later also to calcium deposit in the tissues, primarily in the kidneys (nephrolithiasis, nephrocalcinosis) and the vessels.

The symptoms of an intoxication are nonspecific and may appear as nausea, vomiting, at first often as diarrhoea, later on as obstipation, anorexia (loss of appetite), weakness, headache, muscle and joint pain, muscle weakness as well as persistent drowsiness, azotemia (increased nitrogen concentration in blood), polydipsia (excessive thirst) and polyuria (increased urge to urinate), finally as exsiccosis (dehydration). Typical laboratory test results are hypercalcemia (increased calcium concentration in blood), hypercalciuria (increased calcium concentration in urine) as well as increased serum levels of 25-hydroxycalciferol.

Treatment of overdose

In case of an overdose measures for the treatment of the often long lasting and potentially threatening hypercalcemia (increased calcium concentration in blood) are required.

The first measure is to stop the administration of the vitamin D product; a normalization of the hypercalcemia due to vitamin D intoxication lasts for several weeks.

Graduated according to the extent of the hypercalcemia calcium low or calcium free nutrition, plenty intake of fluids, forced diuresis by means of the drug furosemide as well as the administration of glucocorticoids (drugs for treatment of certain allergic diseases) and calcitonine (hormone regulating the calcium concentration in the blood) may be applied.

Infusions of isotonic saline solution (3-6 l in 24 hours) with addition of furosemide (drug to increase diuresis) as well as possibly 15 mg/kg BW/h sodium edetate (drug binding calcium in the blood) under continuous calcium and ECG-control have a quite reliable calcium lowering effect in patients with sufficient kidney function. Haemodialysis (blood purification) with calcium free dialysis fluid is indicated in case of oliguria (low output of urine).

A specific antidote does not exist.

If you assume that application of D₃-Vicotrat has been forgotten

If you assume that the previous application has been forgotten address to your doctor or pharmacist.

If you stop using D₃-Vicotrat

In case of an interruption or premature termination of the treatment your discomfort may worsen again or reappear. Please ask your doctor on this!

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.

Side effects or signs to which you should pay attention and measures, if you are concerned

If you are affected by one of the mentioned side effects, do not further use D₃-Vicotrat and consult your doctor as soon as possible.

The side effects of vitamin D result from the increased serum calcium level due to overdose. Depending on dosage and duration of the therapy a severe and long-lasting hypercalcemia can appear with acute symptoms (arrhythmia, nausea, vomiting, psychic symptoms and impaired consciousness) and chronic symptoms (polyuria, polydipsia, anorexia, weight loss, kidney stone formation, nephrocalcinosis, extraosseous calcifications). In individual cases fatal courses have been described.

Reporting of side effects

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

You can also report side effects directly via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store D₃-Vicotrat

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

Do not use this medicine after the expiry date which is stated on the carton after "Verwendbar bis" and on the label after "Verw. bis". The expiry date refers to the last day of that month.

After opening of the ampoules any leftover content must be discarded.

6. Contents of the pack and other information

What D₃-Vicotrat contains

- The active substance is cholecalciferol (vitamin D₃).

1 ampoule with 1 ml of solution for injection contains:
2.5 mg cholecalciferol corresponding to 100 000 IU of vitamin D₃.

- The other ingredients are sodium dihydrogen phosphate dihydrate; sodium hydroxide; sorbitol liquid 70% (crystallizing); polysorbate 80; triglycerides, medium-chain; water for injections.

What D₃-Vicotrat looks like and contents of the pack

D₃-Vicotrat is a clear to opalescent, slightly yellowish solution.

In D₃-Vicotrat, the fat-soluble vitamin D₃ is dispersed with solubilizers in water. Hereby an opalescent "solution" develops, appearing more or less turbid in incident light (Tyndall effect). The turbidity of the solution may be influenced by concentration and temperature and the solution may tend to emulsify. However, an appearing turbidity does not influence the effectiveness of the preparation.

D₃-Vicotrat is available in packages of 5 ampoules with 1 ml of solution for injection each.

Marketing Authorisation Holder

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