Package leaflet: Information for the user

D_3-Vicotrat®

100,000 I.U., injection solution

Active substance: Cholecalciferol

Read all of this leaflet carefully before you start using this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT D_3-VICOTRAT IS AND WHAT IT IS USED FOR

1.1 D_3-Vicotrat contains vitamin D_3 which is a hormone regulating the calcium and phosphate metabolism.

1.2 D_3-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. BEFORE YOU USE D_3-VICOTRAT

2.1 Do not use D_3-Vicotrat

- if you are allergic (hypersensitive) to cholecalciferol or any of the other ingredients of D_3-Vicotrat;
- in case of hypercalcemia (increased calcium concentration in blood) and/or
- in case of hypercalciuria (increased calcium concentration in urine);
- during pregnancy and lactation.

2.2 Take special care with D_3-Vicotrat

- if you tend to form kidney stones containing calcium (also in the anamnesis);
- 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 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;
- 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;
- if your mobility is reduced (e.g. due to a cast);
- if you are treated with derivatives of benzothiadiazine (drugs to increase diuresis);
- during long-term therapy with D_3-Vicotrat. In this case the calcium levels in blood and urine should be monitored, and the kidney function should be checked by measuring the serum creatinine every 3 to 6 months. 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 a 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. In this case the dosage of vitamin D from D_3-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.

2.3. Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 D_3-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 D_3-Vicotrat should be chosen.

2.4 Driving and using machines

No special precautions have to be taken when driving or operating machines.

2.5 Important information about some of the ingredients of D_3-Vicotrat

D_3-Vicotrat contains sorbitol. Please ask your doctor for advice before taking D_3-Vicotrat, if you know that you are suffering from intolerance to certain sugars.

2.6 Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of the following active substances or groups of drugs can be influenced by simultaneous treatment with D_3-Vicotrat:

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.

The following active substances or groups of drugs can influence the effect of D_3-Vicotrat during simultaneous treatment:

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.

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 D_3.

The simultaneous administration of **glucocorticoids** (drugs for treatment of certain allergic diseases) can reduce the effect of vitamin D_3.

Only in exceptional cases and under serum calcium controls D_3-Vicotrat should be combined with metabolic products or **analogues of vitamin D**.

3. HOW TO USE D_3-VICOTRAT

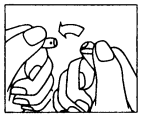
Always use D_3-Vicotrat exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

3.1. 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.

3.2 Unless otherwise prescribed by your doctor, the usual dose is ½ - 1 ampoule (50,000 to 100,000 I.U. vitamin D) as a single dose in individual intervals (normal case: every 3 months).

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 D_3-Vicotrat is too strong or too weak.

3.3 If you use more D_3-Vicotrat than you should

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.

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 alleric 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.

3.4 If you forget to use D_3-Vicotrat

Do not use a double dose to make up for a forgotten dose. Continue with the prescribed dosage.

3.5 If you stop using D_3-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 product, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, D_3-Vicotrat can cause side effects, although not everybody gets them.

The following scale of frequency has been established in the evaluation of side effects:

Very common	more than 1 of 10 treated patients
Common	less than 1 of 10, but more than 1 of 100 treated patients
Uncommon	less than 1 of 100, but more than 1 of 1,000 treated patients
Rare	less than 1 of 1,000, but more than 1 of 10,000 treated patients
Very rare	less than 1 of 10,000 treated patients or unknown

4.1 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 D_3-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, extra-osseous 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 to 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 D_3-VICOTRAT

Keep out of the reach and sight of children.

Do not use D_3-Vicotrat after the expiry date which is stated on the carton and label after “Verwendbar bis/Verw. bis:”. The expiry date refers to the last day of that month.

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

Do not store above 25 °C!

6. FURTHER INFORMATION

6.1 What D_3-Vicotrat contains

The active substance is cholecalciferol (vitamin D_3).

1 ampoule with 1 ml of injection solution for intramuscular application contains:

2.5 mg cholecalciferol corresponding to 100,000 IU of vitamin D_3.

The other ingredients are sodium dihydrogen phosphate 2 H_2O, sodium hydroxide, sorbitol solution 70% (crystallizing), polysorbate 80, middle-chained triglycerides, water for injection.

6.2 What D_3-Vicotrat looks like and contents of the pack

D_3-Vicotrat is available in packages of 5 ampoules with 1 ml of injection solution each.

In D_3-Vicotrat the fat-soluble vitamin D_3 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.

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This medicinal product is authorised in the Member States of the EEA under the following names:

Federal Republic of Germany: D_3-Vicotrat®

This package leaflet was last revised in December 2014.