



PACKAGE LEAFLET: INFORMATION FOR THE USER

DEVIT-3 5,000 IU Soft Capsules

Taken by mouth.

Active substance: Each capsule contains 5,000 IU of cholecalciferol equivalent to 125 mcg.

Excipients: Refined sunflower oil, gelatin, glycerin, sorbitol, deionized water, FD&C Red No:3 (Erythrosine, sodium chloride, sodium sulfate, volatile substance).

Read all of this PACKAGE 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 pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you.*

In this leaflet:

- 1. What DEVIT-3 is and what it is used for**
- 2. What you need to know before you take DEVIT-3**
- 3. How to take DEVIT-3**
- 4. Possible side effects**
- 5. How to store DEVIT-3**

1. WHAT DEVIT-3 IS AND WHAT IT IS USED FOR

DEVIT-3 contains cholecalciferol (vitamin D₃) as its active substance. Cholecalciferol is obtained from sheep wool fat.

DEVIT-3 contains vitamin D₃, which regulates calcium uptake and metabolism, and supports calcium incorporation into bone tissue.

DEVIT-3 is presented in cardboard boxes in the form of biconvex, oval, transparent, pink colored soft capsules.

DEVIT-3 is used in the treatment of vitamin D deficiency, to continue the treatment of vitamin D deficiency (maintenance) and to prevent deficiency.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEVIT-3

DO NOT USE DEVIT-3

- If you are allergic (hypersensitive) to cholecalciferol (vitamin D₃) or any of the other ingredients,
- If you have hypercalcemia (high levels of calcium in your blood) or hypercalciuria (high levels of calcium in your urine), or if you have a disease that can result in hypercalcemia and hypercalciuria,
- If you have hypervitaminosis D (high levels of vitamin D in your blood),
- If you have kidney stones (nephrolithiasis) or kidney calcification (nephrocalcinosis),



- If you have severe kidney failure,
- If you are under 12 years of age.

If any of the above applies to you, talk to your doctor or pharmacist before using DEVIT-3.

TAKE SPECIAL CARE with DEVIT-3

- If you have heart disease or narrowing of your arteries,
- If you have sarcoidosis (a specific connective tissue disease that can affect the lungs, skin, joints),
- If you are taking medicines containing vitamin D,
- If you have moderate to mild kidney problems.

Your doctor may ask you to have regular blood tests to check the level of calcium in your blood.

Although the routine use of medicines containing vitamin D during pregnancy is not recommended, they should be used under the supervision of a physician when necessary.

The maximum dose should not exceed 1,000 IU/day in the use of medicines containing vitamin D for the purpose of prevention treatment during pregnancy.

Please consult your doctor even if these warnings were applicable to you at any time in the past.

Use in children

DEVIT-3 is not recommended for use in children under 12 years of age.

Taking DEVIT-3 with food and drink

You should swallow this medicine whole with a glass of water. You may take it with or without food.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

If you are pregnant, likely to be pregnant, or thinking of becoming pregnant, consult your doctor or pharmacist before using this medicine. Do not use DEVIT-3 without consulting your doctor because taking too much vitamin D can harm your baby.

Although the routine use of medicines containing vitamin D during pregnancy is not recommended, they should be used under the supervision of a physician when necessary.

The maximum dose should not exceed 1,000 IU/day in the use of medicines containing vitamin D for the purpose of prevention treatment during pregnancy.

If you realize that you are pregnant during your treatment consult your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

DEVIT-3 can be used while breastfeeding. Vitamin D₃ passes into breast milk. Additional vitamin D intake to the breastfed child should be considered in this situation.



Infants of nursing mothers who take therapeutic doses of vitamin D are at risk of increased blood calcium levels (hypercalcemia).

If you are breastfeeding, consult your doctor or pharmacist before using this medicine.

Driving and using machines

DEVIT-3 has no known influence on the ability to drive and use machines.

Important information about some of the ingredients of DEVIT-3

DEVIT-3 contains sorbitol. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines

In particular, tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines, or if you are using any other medicines:

- Medicines used in epilepsy such as barbiturates or other anticonvulsants (e.g. carbamazepine, phenobarbital, phenytoin, and primidone) may reduce the effectiveness of vitamin D,
- Cholestyramine (used to treat high cholesterol) may cause reduced absorption of vitamin D,
- Phenytoin or barbiturates (medicines used in epilepsy),
- Laxatives containing paraffin oil,
- Thiazide diuretics (medicines used to treat high blood pressure) reduce urinary calcium excretion and may increase the risk of hypercalcemia,
- Glucocorticosteroids (used to treat inflammation) can reduce the effects of vitamin D,
- Cardiac glycosides (medicines to control your heart rate) e.g. digoxin. Your doctor can monitor your heart with an electrocardiogram (ECG) and measure calcium levels in your blood,
- Medicines used in the treatment of tuberculosis such as rifampicin, isoniazid,
- Actinomycin (used for chemotherapy),
- Imidazole, ketoconazole, itraconazole (used to treat fungus),
- Orlistat (used for weight loss) may cause decreased absorption of vitamin D,
- Medicines containing vitamin D, calcium supplements,
- Medicines that cause reduced fat absorption, such as colestipol (used to lower cholesterol) may cause decreased absorption of vitamin D,
- Phosphate infusion should not be administered in case of low hypercalcemia of hypervitaminosis D due to the danger of metastatic calcification (precipitation of calcium salts in normal tissue due to hypercalcemia or hyperphosphatemia).

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

3. HOW TO TAKE DEVIT-3

Instructions for proper use and dose/frequency of administration

Always take DEVIT-3 as prescribed by your doctor. Consult your doctor or pharmacist if you are not sure about the use of the medicine. Your doctor will decide how to use the medicine. Use the medicine according to the advice of your doctor.



Age Group	Recommended Dose for Prophylaxis / Maintenance	Vitamin D Deficiency Treatment Dosage		Maximum Tolerated Dose for Long-Term Treatment and Prophylaxis in Risk Groups
		Daily Treatment**	Weekly Administration	
Newborn	400 IU/day (10 mcg/day)	1,000 IU/day (25 mcg/day)	No	1,000 IU/day (25 mcg/day)
1 month to 1 year	400 IU/day (10 mcg/day)	2,000-3,000 IU/day (50-75 mcg/day)	No	1,500 IU/day (37.5 mcg/day)
1 year to 10 years	400-800* IU/day (10-20 mcg/day)	3,000-5,000 IU/day (75-125 mcg/day)	No	2,000 IU/day (50 mcg/day)
11 years to 18 years	400-800* IU/day (10-20 mcg/day)	3,000-5,000 IU/day (75-125 mcg/day)	No	4,000 IU/day (100 mcg/day)
Adults over 18 years	600-1,500 IU/day (15-37.5 mcg/day)	7,000-10,000 IU/day (175-250 mcg/day)	50,000 IU/week (1250 mcg/week)***	4,000 IU/day (100 mcg/day)

* Can be increased up to 1,000 IU when necessary.

** Can be taken up to 6-8 weeks.

*** If weekly dosage is preferred to daily dosage, a single dose of 50,000 IU can be used for up to 6-8 weeks. More than 50,000 IU of vitamin D at once is not recommended.

Although the routine use of medicines containing vitamin D during pregnancy is not recommended, they should be used under the supervision of a physician when necessary.

The maximum dose should not exceed 1,000 IU/day in the use of medicines containing vitamin D for the purpose of prevention treatment during pregnancy.

Route and method of administration

DEVIT-3 capsules should be taken by mouth. They should be swallowed whole with a glass of water. You can use the medicine with or without food.

Different age groups

Use in children

It is applied as stated in the section 'Instructions for proper use and dose/frequency of administration'. DEVIT-3 5,000 IU soft capsule should not be used in children under 12 years of age.

Other forms of DEVIT-3 may be more suitable for children. You can ask your doctor or pharmacist about this.

Use in elderly

The dosage is applied as in adults.

Use in special conditions

Liver failure

No dose adjustment is required in patients with liver failure.

Kidney failure

DEVIT-3 should not be used in patients with severe kidney impairment.

If you feel that the effect of DEVIT-3 is too strong or too weak, talk to your doctor or pharmacist.

If you take more DEVIT-3 than you should

If you have accidentally used more than the prescribed dose or if a child has taken this medicine by



mistake, please talk to your doctor for advice or seek emergency medical attention to assess the risks.

Excessive amounts of vitamin D cause hypercalcemia by causing increased levels of calcium in the blood and urine. Hypercalcemia symptoms are nausea, vomiting, first diarrhea and then constipation, thirst, stomachache, mental disorders, bone pain, loss of appetite, fatigue, headache, muscle and joint pain, muscle weakness, excessive thirst, excessive urination, formation of kidney stones, kidney calcification, kidney failure, deposition of calcium in soft tissues, changes in ECG measurements, irregular heartbeat and inflammation of the pancreas.

If you have taken more DEVIT-3 than you should, talk to a doctor or pharmacist.

If you forget to take DEVIT-3

If you forget to take your capsule, take it as soon as possible. Then take the next dose at the correct time, in accordance with the instructions given to you by your doctor. 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 stop taking DEVIT-3

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, DEVIT-3 can cause side effects in patients with sensitivity to its ingredients.

If you experience any of the following, stop using DEVIT-3 and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Swelling of the face, lips, tongue, or throat
- Difficulty in swallowing
- Hives and shortness of breath

All of these are very serious side effects. If you have one of these, it means you have a serious allergy to DEVIT-3. You may need immediate medical attention or hospitalization.

Side effects are classified as indicated on following frequencies:

- Very common : may be seen in at least 1 in 10 patients.
- Common : may be seen in less than 1 in 10 but more than 1 in 100 patients.
- Uncommon : may be seen in less than 1 in 100 but more than 1 in 1,000 patients.
- Rare : may be seen in less than 1 in 1,000 patients but more than 1 in 10,000 patients.
- Very rare : may be seen in less than 1 in 10,000 patients.
- Not known : cannot be estimated from the available data.

Side effects related to DEVIT-3 may include the following:

Uncommon

- Hypercalcemia (too much calcium in your blood)
- Hypercalciuria (too much calcium in your urine)



Rare

- Skin rash
- Itching
- Hives (urticaria)

If you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medication.

5. HOW TO STORE DEVIT-3

Keep DEVIT-3 out of the sight and reach of children and in its original package.

Store this medicine at room temperature below 25°C, and in its original package to protect from light and moisture.

Use this medicine in line with the expiry date.

Expiry date refers to the last day of the month written on the package.

Do not use DEVIT-3 after the expiry date, which is stated on the package.

Do not use DEVIT-3 if you notice any defect on the product and/or its package.

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 protect the environment.

Marketing Authorization Holder

DEVA HOLDING A.Ş.
Küçükçekmece - İstanbul/TURKEY

Manufacturing site

DEVA HOLDING A.Ş.
Kapaklı - Tekirdağ/TURKEY

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