



PACKAGE LEAFLET: INFORMATION FOR THE USER

DEVIT-3 10,000 IU Soft Capsules

Taken by mouth.

Active substance: Each capsule contains 10,000 IU of cholecalciferol equivalent to 250 mcg.

Excipients: Sunflower oil, gelatin, glycerin, sorbitol, deionized water.

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 (known as vitamin D₃) as its active substance. Cholecalciferol is obtained from sheep wool fat. Vitamin D is found in some foods and is also produced by the body when the skin is exposed to sunlight.

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

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

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 high levels of calcium in your blood (hypercalcemia) or in your urine (hypercalciuria),
- If you have severe kidney failure,
- If you have kidney stones,
- If you have a tendency to produce calcium-containing kidney stones (renal stones),
- If you have high levels of vitamin D in your blood (hypervitaminosis D),
- In children under 12 years of age.



TAKE SPECIAL CARE with DEVIT-3

Talk to your doctor before taking DEVIT-3 if you have any of the following:

- Undergoing treatment with certain medicines used to treat heart disorders (e.g. cardiac glycosides such as digoxin),
- Having sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body),
- Taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D,
- Are likely to be exposed to a lot of sunlight whilst using DEVIT-3,
- Taking 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 DEVIT-3,
- Having kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.

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.

Taking DEVIT-3 with food and drink

You should take DEVIT-3 preferably with the main meal to increase the absorption of vitamin D.

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. High doses of vitamin D are not recommended for pregnant women.

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.

If you are breastfeeding, consult your doctor or pharmacist before taking DEVIT-3. Vitamin D passes into breast milk. Treatment with high doses of vitamin D is not recommended for women who are breastfeeding. There is a risk of hypercalcemia in infants of breastfeeding mothers who receive pharmacological doses of vitamin D.



Driving and using machines

There is limited information on the possible effects of DEVIT-3 on your ability to drive or use machines. However, it is not expected that it would affect your ability to drive or operate machinery.

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

Tell your doctor or pharmacist if you are taking or have recently taken or will take any other medicines. This includes medicines you use without a prescription. The medicines you take together with this medicine may be harmful.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Medicines that act on the heart or kidneys, such as cardiac glycosides (e.g. digoxin) or diuretics (e.g. bendroflumethiazide). When used at the same time as vitamin D these medicines may cause a large increase in the level of calcium in the blood and urine. Digitalis toxicity (arrhythmia) of vitamin D may increase. Your doctor can monitor your heart with an electrocardiogram (ECG) and measure calcium levels in your blood.
- Medicines containing vitamin D or eating food rich in vitamin D, such as, some types of vitamin D-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 processes vitamin D.

The following medicines may interfere with the effect or the absorption of vitamin D:

- Antiepileptic medicines (such as phenytoin) or medicines to treat sleep disorders and epilepsy (barbiturates such as phenobarbitone). These medicines may reduce the effect of vitamin D.
- Glucocorticoids (steroid hormones such as hydrocortisone and prednisolone). These medicines may decrease the effect of vitamin D,
- Medicines that lower the level of cholesterol in the blood (such as cholestyramine or colestipol). These can reduce the absorption of vitamin D.
- Thiazide diuretics (edema relievers) may increase the concentration of calcium in the blood.
- Some medicine used for weight loss (such as orlistat) that reduce the amount of fat your body absorbs. These medicines may decrease the absorption of vitamin D.
- Some laxatives (like paraffin oil). These medicines may cause reduced absorption of vitamin D.

If you are unsure about the types of medicines you are using, consult your doctor or pharmacist.

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

Always use DEVIT-3 exactly as your doctor or pharmacist has told you. If you are not sure, check with your doctor or pharmacist. DEVIT-3 capsules should be taken orally (through your mouth).

Instructions for proper use and dose/frequency of administration

A capsule of this medicine should be swallowed whole with a glass of water, preferably during a main meal.



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.

The physician must decide individually whether further treatment (follow-up or long-term) with DEVIT-3 capsules is necessary.

During long-term therapy, calcium levels of your blood and urine should be monitored regularly and your kidney function should be tested by serum creatinine measurement. If necessary, the dosage should be adjusted according to the blood calcium values (see Section 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEVIT-3).

Route and method of administration

Swallow the capsules whole (without chewing) with a glass of water. DEVIT-3 capsules should preferably be taken with the main meal.

Different age groups

Use in children

DEVIT-3 10,000 IU soft capsules should not be used in children under 12 years of age as they may not be able to swallow the capsules or there may be a risk of suffocation.

Use in elderly

The dosage is applied as in adults.



Use in special conditions

Kidney/Liver failure

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

No data is available on liver failure.

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 accidentally take too many capsules or someone else uses your medicine, you should tell your doctor right away or contact the nearest emergency department. Show the remaining medicine or the empty package to the doctor.

According to laboratory tests, an overdose can lead to increased levels of calcium in the blood (hypercalcemia) and urine (hypercalciuria).

Signs and symptoms of overdose may include: nausea (feeling sick), vomiting, excessive thirst, large volumes of urine production, constipation, dehydration, stomachache, muscle weakness, fatigue, loss of appetite, kidney problems and irregular heartbeat in severely ill patients.

In case of overdose, your doctor will treat you accordingly.

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, do not worry and take it as soon as you remember. Then take the next dose at the correct time, in accordance with the instructions given to you by your doctor.

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, DEVIT-3 can cause side effects, although not everyone gets them.

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

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



Rare

- Skin rash
- Itching
- Hives

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.

Use this medicine in line with the expiry date.

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

Expiry date refers to the last day of the month written 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

This package leaflet was approved on 27/03/2021.