



PACKAGE LEAFLET: INFORMATION FOR THE USER

DEVIT-3 50,000 IU Soft Capsules

Taken by mouth.

Active substance: Each capsule contains 50,000 IU of cholecalciferol equivalent to 1.25 mg.

Excipients: Refined sunflower oil, gelatin, glycerin, sorbitol, deionized water, iron oxide yellow.

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 produced from sheep wool fat.

It is presented in cardboard boxes in the form of biconvex, oval, mustard yellow colored soft capsules.

DEVIT-3 is used in the therapy, maintenance and prophylaxis (prevention) of Vitamin D 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 any disease that causes these two,
- If you have kidney stones or a tendency to produce calcium-containing kidney stones,
- If you have serious kidney problems,
- If you have high levels of Vitamin D in your blood (hypervitaminosis D),
- In children if they are under 18 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

- Undergoing treatment with certain medicines used to treat heart disorders (e.g. cardiac glycosides)



such as digoxin),

- Having sarcoidosis (multisystem, specific connective tissue disease that can affect the lungs, skin, joints, heart and kidneys),
- Taking medicines containing Vitamin D, or eating foods or milk enriched with Vitamin D,
- Being treated with diuretics (benzothiadiazine),
- Being immobilized,
- Having pseudo-hypoparathyroidism (a type of parathyroid gland failure),
- 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.

Use in children

DEVIT-3 should not be used in children under 18 years of age.

Taking DEVIT-3 with food and drink

The capsule should be swallowed whole with a glass of water. It is recommended to take it with food. DEVIT-3 is easier to absorb by your body if it is taken with a meal.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

If you are pregnant, likely to be pregnant, or planning to become pregnant, consult your doctor or pharmacist before using this medicine. Since DEVIT-3 50,000 IU Soft Capsules contain high doses of Vitamin D, it is not recommended to be used by pregnant women.

Excessive doses of Vitamin D₃ should be avoided during pregnancy, as, in children, long-term elevation of calcium in the blood may lead to delayed physical and mental development, narrowing of the vessels called supravalvular aorta, and retinopathy (defect in the retina of the eye).

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 the treatment consult your doctor immediately.



Breastfeeding

Consult your doctor or pharmacist before using the medicine.

If you are breastfeeding, consult your doctor or pharmacist before using this medicine. Vitamin D₃ and its metabolites pass into breast milk. Since DEVIT-3 50,000 IU Soft Capsules contain high doses of Vitamin D, it is not recommended for use by breastfeeding women. There is a risk of hypercalcemia in babies of breastfeeding mothers who receive pharmacological doses of Vitamin D.

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

Tell your doctor or pharmacist if you are using or have recently used any medication. This is especially important if you are taking any of the following:

- 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 D₃ these medicines may cause a large increase in the level of calcium in the blood and urine. Administration of Vitamin D may increase the risk of digitalis toxicity (arrhythmia). Your doctor can monitor your heart with an electrocardiogram (ECG) and measure the level of calcium in your blood.
- Medicines containing Vitamin D₃ or eating food rich in Vitamin D₃, 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 D₃.
- Medicines used to treat tuberculosis (rifampicin, isoniazid).

The following medicines because they may reduce the effect or the absorption of Vitamin D₃:

- Antiepileptic medicines (anticonvulsants) or barbiturates. These medicines may reduce the effect of Vitamin D₃.
- Glucocorticoids (steroid hormones such as hydrocortisone and prednisolone). These may reduce the effect of Vitamin D₃.
- Thiazide diuretics may increase the concentration of calcium in the blood.
- Medicines that lower the level of cholesterol in the blood (such as cholestyramine or colestipol) may reduce the absorption of Vitamin D.
- Certain medicines for weight loss that reduce the amount of fat your body absorbs (such as orlistat) may reduce the absorption of Vitamin D.
- Certain laxatives (such as liquid paraffin).

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 this medicine.

Your doctor will decide how the medicine will be used. Use it 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 (1,250 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 and swallowed whole with a glass of water. It is recommended to take your capsule during a main meal. When DEVIT-3 is taken with food, your body absorbs the medicine more easily.

Different age groups

Use in children

DEVIT-3 should not be used by children under 18 years of age.

Use in elderly

It should be used as in adults.

Use in special conditions

Kidney/Liver failure

DEVIT-3 should not be used in patients with severe kidney failure. It should be used with caution in cases of mild to moderate kidney failure. No dose adjustment is required for patients with 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 or your child have accidentally taken more DEVIT-3 than prescribed, talk to your doctor about



this immediately or go to the nearest hospital emergency department and remember to take your medicines' packages with you.

The most common symptoms of overdose are: nausea, vomiting, first diarrhea and then constipation, loss of appetite, fatigue, headache, pain in the muscles and joints, muscle weakness, persistent insomnia, excessive levels of nitrogen in the blood, excessive thirst, the production of large amounts of urine over 24 hours, dehydration (water loss in the body), high levels of calcium in the blood (hypercalcemia), high levels of calcium in the urine (hypercalciuria), elevated Vitamin D₃ metabolites in the blood, shown by lab tests.

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 DEVIT-3, take it as soon as you remember. Then take the next dose at the correct time. 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.

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.

Possible 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 directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

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 in order 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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