



PACKAGE LEAFLET: INFORMATION FOR THE USER

DEVIT-3 1,000 IU Soft Capsules Taken by mouth.

Active substance: Each capsule contains 1,000 IU of cholecalciferol equivalent to 25 mcg.

Excipients: Refined sunflower oil, gelatin, glycerin, sorbitol, deionized water, FD&C yellow no:5.

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 (obtained from sheep wool fat) as its active substance, (cholecalciferol is also known as vitamin D₃).

DEVIT-3 is presented in cardboard boxes in the form of oval, transparent, dark yellow 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.

DEVIT-3 1.000 I.U. soft capsule contains vitamin D₃ equivalent to 25 mcg.

The active ingredient, cholecalciferol, is similar to the cholecalciferol found in the human body. It is produced in the body as a result of certain diets and when the skin is exposed to the sun.

Vitamin D deficiency can occur when your diet or lifestyle is not enough for you to get sufficient vitamin D, or when your body needs more vitamin D (for example, if you are pregnant).

If you are pregnant or planning to become pregnant and need extra vitamin D, do not use DEVIT-3 without consulting your doctor.



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 urine (hypercalciuria),
- If you have severe kidney failure, kidney stones or a tendency to form kidney stones,
- If you have kidney calcification (nephrocalcinosis),
- If you have high levels of vitamin D (hypervitaminosis D) in your blood,
- If you are under 12 years of age.

Take special care with DEVIT-3

- If you have heart disease or narrowing of your arteries,
- If you suffer from sarcoidosis (a multi-system chronic inflammatory disease that can affect the lungs, heart, and kidneys), you are at risk of overconverting vitamin D to its active form.
- If you are taking medications containing vitamin D or taking food or drinking vitamin D-rich milk, talk to your doctor or pharmacist before using DEVIT-3.
- It should be used with caution in patients with mild and moderate renal impairment, and its effects on calcium and phosphate levels should be monitored.

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

The routine use of medicines containing vitamin D during pregnancy is not recommended. However, 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 prophylaxis 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

Capsules should be swallowed with a glass of water, preferably between meals.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

If you are pregnant, likely to be pregnant or planning to become pregnant, consult your doctor or pharmacist before using this medicine. If you need extra vitamin D, 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 during breastfeeding with the advice of a doctor. Vitamin D₃ passes into breast milk. There is a risk of increased blood calcium levels (hypercalcemia) in infants of breastfeeding mothers who receive therapeutic doses of vitamin D. Supplemental vitamin D intake to the breastfed child should be considered in this situation.

If you are breastfeeding, consult your doctor or pharmacist before using this medicine. If you need extra vitamin D, do not use DEVIT-3 without consulting your doctor because taking too much vitamin D can harm your baby.

Driving and using machines

DEVIT-3 is not expected to affect the ability to drive and use machines.

Important information about some of the ingredients of DEVIT-3

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

DEVIT-3 contains FD&C Yellow No:5, which is a azo dye. It may cause allergic reactions.

Concomitant use with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take the following medicines. This includes medicines you buy without a prescription.

Tell your doctor or pharmacist if you are using any of the following drugs:

- Medicines used in epilepsy such as barbiturates or other anticonvulsants (e.g. carbamazepine, phenobarbital, phenytoin, and primidone)
- Other vitamin D containing medications such as multivitamins
- Medicines that control your heart rate (eg digoxin, digitoxin)
- Diuretics such as bendroflumethiazide
- Thiazide diuretics (drugs used to treat high blood pressure)
- Calcium supplements
- Medicines used in the treatment of tuberculosis such as rifampicin, isoniazid
- Medicines that interact with fat absorption such as orlistat, cholestyramine and liquid paraffin,
- Medicines used in the treatment of fungal infections such as ketoconazole and itraconazole,
- Actinomycin (used in the treatment of some types of cancer), which can interact with the metabolism of vitamin D
- Glucocorticosteroids (steroid hormones such as hydrocortisone or prednisolone)

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 Dose		Maximum Tolerated Dose for Maintenance 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.

If you have problems with vitamin D absorption or another condition such as liver disease, the dose given to you may be different and depends on your medical condition.

It is important not to exceed the recommended dose.

Route and method of administration

DEVIT-3 capsules should be taken by mouth. The capsule should be swallowed whole with water, preferably between meals.

Different age groups

Use in children

DEVIT-3 1,000 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

Used as in adults.

Use in special conditions

Kidney impairment

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



Liver impairment

No dose adjustment is required in patients with liver 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 accidentally take 1 capsule more than the prescribed dose, this will not affect you negatively, but if you have used too many capsules, talk to your doctor or seek emergency medical attention.

An overdose can cause an excess of vitamin D. An excess of vitamin D causes high calcium levels in the blood. This condition can cause serious damage to soft tissues and kidneys.

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 possible, take the capsules, the box and this package leaflet with you to show your doctor.

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 right time as your doctor has told you. However, if the missed dose is close to the next dose, skip the missed dose and take the next dose as normal.

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 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.

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

Uncommon

- Too much calcium in the blood (hypercalcemia). You may experience nausea or feeling sick, loss of appetite, constipation, stomach pain, feeling very thirsty, muscle weakness, drowsiness or



confusion.

- Too much calcium in your urine (hypercalciuria).

Rare

- Skin rash
- Itching
- Itchy rash (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.

The expiration date refers to the last day of that month.

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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