



PACKAGE LEAFLET: INFORMATION FOR THE USER

DEVIT-3 20,000 IU Soft Capsules

Taken by mouth.

Active substance: Each capsule contains 20,000 IU of cholecalciferol equivalent to 500 mcg.

Excipients: Refined sunflower oil, gelatin), glycerin, sorbitol, deionized water, FD&C Yellow No:6 (Sunset yellow, sodium chloride).

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).

It is used in the treatment, maintenance and prophylaxis (prevention) of vitamin D deficiency.

DEVIT-3 is presented in cardboard boxes in the form of biconvex, oval, transparent, orange 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 or any of the other ingredients in DEVIT-3,
- If you have high levels of calcium in your blood (hypercalcemia) or in your urine (hypercalciuria),
- If you have serious kidney problems,
- If you have a tendency to produce calcium-containing kidney stones,
- If you have high levels of vitamin D in your blood (hypervitaminosis D).
- In children if they are under 12 years of age, since they may not be able to swallow the capsules and may pose a choking hazard.



TAKE SPECIAL CARE with DEVIT-3

If any of the following conditions apply to you, consult your doctor or pharmacist before you start using the medicine:

- 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,
- Vitamin D therapy may preclude detecting the presence of previously undiagnosed primary hyperparathyroidism (oversecretion of parathyroid hormone). Therefore, serum calcium levels should be checked 1 month after the loading dose or after primary hyperparathyroidism appears.
- 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.

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.

Highest tolerated dose for maintenance (continued dose) treatment and prophylaxis (prevention) of risky groups (see section 3. How to take DEVIT-3):

Newborn: 1,000 IU/day (25 mcg/day)

1 month to 1 year: 1,500 IU/day (37.5 mcg/day)

1 year to 10 years: 2,000 IU / day (50 mcg/day)

11 years to 18 years: 4,000 IU / day (100 mcg/day)

Adults over 18 years of age: 4,000 IU/day (100 mcg/day)

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 this medicine with a large meal to help your body absorb the vitamin D.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

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.

Not recommended for use in breast-feeding women.



Driving and using machines

There is limited information on the possible effects of this medicine 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.

DEVIT-3 contains sunset yellow, which can cause allergic reactions.

Taking 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. Taking some medicines together can be harmful.

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

- Rifampicin may reduce the effectiveness of cholecalciferol as it stimulates liver enzymes.
- Isoniazid may reduce the effectiveness of DEVIT-3 as it suppresses the activation of cholecalciferol.
- Phosphate administration should not be used to reduce blood calcium from excess vitamin D due to the danger of calcium deposits in the tissues.
- 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.
- Medicines containing vitamin D or eating food rich in vitamin D, such as, some types of vitamin D-enriched milk.
- Due to its vitamin D content, it should not be used with calcium in patients with kidney failure.
- 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 because they can 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),
- Glucocorticoids (steroid hormones such as hydrocortisone and prednisolone). These can decrease the effect of vitamin D,
- Medicines that lower the level of cholesterol in the blood (such as cholestyramine or colestipol),
- Certain medicines for weight loss that reduce the amount of fat your body absorbs (such as orlistat),
- Certain laxatives (such as liquid paraffin).

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

Instructions for proper use and dose/frequency of administration

Each soft capsule contains 20,000 IU (500 mcg) of Vitamin D₃.

**Use in children**In the prevention and maintenance treatment of vitamin D deficiency for 11 to 18 years of age

One soft capsule of DEVIT-3 20,000 IU once a month, equivalent to a daily dose of 400-800 IU, should be used as recommended by the doctor.

In the treatment of vitamin D deficiency for 11 to 18 years of age

One soft capsule of DEVIT-3 20,000 IU once or twice a week, equivalent to a daily dose of 3,000-5,000 IU, should be used as recommended by the doctor.

Use in adultsIn the prevention and maintenance treatment of vitamin D deficiency

One soft capsule of DEVIT-3 20,000 IU once or twice a month, equivalent to a daily dose of 600-1,500 IU, should be used as recommended by the doctor.

In the treatment of vitamin D deficiency

One soft capsule of DEVIT-3 20,000 IU every two days, equivalent to a daily dose of 7,000-10,000 IU, should be used as recommended by the doctor. Follow-up 25(OH)D measurements should be made approximately three to four months after starting the maintenance therapy to confirm that the target level has been reached.

Your doctor will decide how to use the medicine. 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 (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 should be taken by mouth.



Different age groups

Use in children

Not recommended for use in children aged 0 to 12 years.

Use in elderly

No dose adjustment is required in the elderly.

Use in special conditions

Liver failure

No data available.

Kidney failure

Due to the vitamin D content of this medicine, it should not be used in combination with calcium in patients with kidney 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

Show any left-over medicine or the empty packet to the doctor.

An overdose can lead to increased levels of calcium in the blood (hypercalcemia) and in the urine (hypercalciuria), shown by lab tests.

Signs and symptoms of an overdose can be nausea (feeling sick), vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration.

Your doctor will treat you accordingly in case of an overdose.

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

If you stop taking DEVIT-3

No effect is expected.

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 may include the following:

Uncommon

- Too much calcium in your blood (hypercalcemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness.-
- 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.

Use this medicine in line with the expiry date.

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

This package leaflet was approved on 04/08/2022.