PACKAGE LEAFLET: INFORMATION FOR THE USER

DEVIT-3 50.000 IU/15 ml Oral Drops
For oral administration

Active substance: Each 15 ml (total volume) bottle contains 1.25 mg = 50.000 IU vitamin D_3 (obtained from lanolin from sheep wool)
Excipients: Butylated hydroxyanisole, sunflower seed oil.

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

- DEVIT-3 contains vitamin D_3 as drug substance. Vitamin D is obtained from lanolin from sheep wool.
- DEVIT-3 is supplied in 20 ml glass bottles with a dropper in carton boxes.
- DEVIT-3 is used in treatment of vitamin D deficiency, maintenance and prophylaxis.

2. BEFORE YOU TAKE DEVIT-3

DO NOT take DEVIT-3
- If you have allergy (hypersensitivity) to cholecalciferol (vitamin D_3) or any of the other ingredients
- If you have severe high blood pressure (hypertension)
- If you have severe arterial stiffness (atherosclerosis)
- If you have active pulmonary tuberculosis, you should not use high doses of this medicine for long period of time
- D hypervitaminosis (a disease caused by excessive intake or accumulation of vitamin D. Its symptoms are loss of appetite, constipation, blurred vision and muscle weakness)
- Hypercalcemia (high blood levels of calcium) or hypercalciuria (high urine levels of calcium)
- If you have kidney stone (containing calcium)
- If you have sensitivity to calcium

TAKE SPECIAL CARE with DEVIT-3

- If you are not active enough,
- If you are using benzothiadiazine-derivative diuretics (promoting production of urine)
- If you have history of kidney stones,
- If you have sarcoidosis,
- If you have pseudohypoparathyroidism (a kind of parathyroid gland insufficiency),
- If you have renal disorder,
- If you are taking another drug containing vitamin D and its derivatives.

Vitamin D has a relatively low therapeutic index in infants and children. If hypercalcemia lasts for a long period of time, it causes mental and physical retardation in infants. There is risk of hypercalcemia in infants of breast-feeding mothers who take Vitamin D at pharmacological dose.

The highest tolerated dose for maintenance treatment and prophylaxis of risk groups is 4000 IU/day (100 µg/day) for children over 11 years of age and adults.

If these warnings are valid for you, even if for a period in the past, please consult your doctor.

Taking DEVIT-3 with food and drink
It does not have any known interaction with food and drink.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
It should not be used during pregnancy unless it is necessary.

Routine use of vitamin D-containing medicines during pregnancy is not recommended, however it should be used under doctor control if needed.

The maximum dosage of vitamin D-containing medicines used for prophylaxis in pregnancy should not exceed 1000 IU/day.

During your treatment, if you realize that you're pregnant, consult your doctor or pharmacist immediately.

Breast-feeding
Vitamin D is excreted in breast milk.
Consult your doctor or pharmacist before taking this medicine.

Driving and using machines
No specific data is available on its effects on ability to drive and use machines

Important information about some inactive ingredients of DEVIT-3
DEVIT-3 contains butylated hydroxyanisole; however, it is not expected to exert any effect due to its method of administration.

Taking other medicines
Anticonvulsants, hydantoin, barbiturates or pyrimidon (drugs used in epilepsy), rifampicin (an antibiotic used in the treatment of tuberculosis) and glucocorticoids (medicines which are similar to hormones) may decrease the action of Vitamin D due to hepatic microsomal enzyme induction.

Concurrent use with vitamin D may antagonize calcitonin, etidronat, gallium nitrate, pamidronate or plicamycin in the treatment of hypercalcemia (high blood levels of calcium).
Simultaneous administration of calcium-containing preparations in high doses or diuretics and thiazides (which promote the production of urine) increases the risk of hypercalcemia (high blood levels of calcium). Careful monitoring of serum calcium concentrations is essential during long-term therapy.
Concurrent use of vitamin D with other drugs containing vitamin D or its derivatives is not recommended because of increased potential for toxicity.
Isoniazid (used in the treatment of tuberculosis) may reduce the effectiveness of vitamin D_3.
Patients treated with cardiac glycosides may be susceptible to high calcium levels and therefore ECG (heart graph) parameters and calcium levels of these patients must be absolutely monitored.
Drugs leading to fat malabsorption, e.g. orlistat (used in the treatment of obesity) and colestyramin (used in the treatment of cholesterol), may impair the absorption of vitamin D.

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

3. HOW TO TAKE DEVIT-3

Instructions for proper use and dose/frequency of administration
Always take DEVIT-3 exactly as your doctor has told you. Consult your doctor or pharmacist when you are not sure.
1 ml DEVIT-3 solution contains 25 drops.

Your doctor will decide how you will use this medicine, follow his/her instructions.

Age group	Prevention treatment/ Long term treatment Recommended dosage	Vitamin D Deficiency treatment dosage		Maximum tolerated dosage for Long term treatment and prevention treatment in risk groups
		Daily treatment**	Weekly administration	
Newborn	400 IU/day (10 µg/day)	1000 IU/day (25 µg/day)	No	1000 IU/day (25 µg/day)
1 month – 1 year	400 IU/day (10 µg/day)	2000-3000 IU/day (50-75 µg/day)	No	1500 IU/day (37,5 µg/day)
1-10 years	400-800* IU/day (10-20 µg/day)	3000-5000 IU/day (75-125 µg/day)	No	2000 IU/day (50 µg/day)
11-18 years	400-800* IU/day (10-20 µg/day)	3000-5000 IU/day (75-125 µg/day)	No	4000 IU/day (100 µg/day)
Adults over 18 years	600-1500 IU/day (15-37,5 µg/day)	7000-10.000 IU/day (175-250 µg/day)	50.000 IU/week (1250 µg/week)***	4000 IU/day (100 µg/day)

* Can be increased to 1000 IU.
** Can be used 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 Vitamin D at once is not recommended.

Routine usage of vitamin D-containing medicines during pregnancy is not recommended, however when required, it should be used under observation.

The maximum dosage of vitamin D-containing medicines used for prophylaxis in pregnancy should not exceed 1000 IU/day.

Route and method of administration:
DEVIT-3 is administered via oral route.
Oral route is preferred for breast-fed children or for patients to whom injection cannot be administered. For breast-fed children, it can be administered mixed with nutrition.

Different age groups

Use in children
It is used as indicated in the section "Instructions for appropriate use and dose/administration frequency".

Use in the elderly
Dose adjustment is not required.

Use in special conditions

Use in Kidney/Liver Failure
Dose adjustment is not required. In cases which require long-term use of vitamin D_3, renal functions must be monitored. In case of severe renal insufficiency, it should not be used in combination with calcium.

If you have the impression 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 take more DEVIT-3 than you should, you may develop hypercalcemia. Symptoms of hypercalcemia are tiredness, psychiatric symptoms (such as euphoria (having excessive feelings such as joy, confidence and power), dazedness, and disturbed consciousness), nausea, vomiting, loss of appetite, weight loss, thirst, polyuria (increase in the amount of urine), formation of kidney stone, nephrocalcinosis (calcification of the kidneys), excessive calcification in bones and renal failure, changes in ECG, heart rhythm disorder and pancreatitis (inflammation of pancreas).
Treatment: avoid exposure to sunlight. If you have just taken the drug, stomach content can be emptied via vomiting.

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

If you forget to take DEVIT-3
Do not take a double dose to make up for a forgotten dose.

If you stop using DEVIT-3
It is not expected to have any effect after stopping treatment. Do not stop your treatment with DEVIT-3 unless your doctor tells you to do so.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects can occur in persons who are sensitive to the ingredients of DEVIT-3. Frequencies of adverse reactions are not known, as no larger clinical trials have been conducted.

DEVIT-3 has a less possibility of side effects at normal doses and duration. Administration of high doses of vitamin D_3 and uncontrolled prolongation of treatment may lead to following undesirable effects (frequencies of side effects are not known).

Frequencies of undesirable effects are listed as follows:
Very common : affects at least 1 in 10 patients
Common : affects 1 to 10 patients in 100
Uncommon : affects 1 to 10 patients in 1000
Rare : affects 1 to 10 patients in 10.000
Very rare : affects less than 1 patient in 10,000
Unknown : cannot be estimated from the available data.

Unknown:
- Increased levels of calcium in the urine, increased levels of calcium in the blood (hypercalcemia) and increased amount of residual nitrogen in blood (These are detected with blood and urine tests).
- Constipation, flatulence, nausea, abdominal pain, diarrhea
- Hypersensitivity reactions such as pruritus, rash and white or reddish bumps on the skin (urticaria)
- Increase in the amount of urine (polyuria), excessive thirst (polydipsia), lack of urination (anuria)
- Fever

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 to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the icon of 'Side Effect Reporting for Medicines' at www.titck.gov.tr or calling +90 800 314 00 08 as the line of side effect reporting. By reporting side effects you can help provide more information on the safety of this medicine.

If you experience any side effect not included in this package leaflet, inform your doctor or pharmacist.

5. HOW TO STORE DEVIT-3

Keep DEVIT-3 out of the reach and sight of children and in its original package.
Keep at room temperature below 25°C as tightly capped and away from light.

Use it in line with the expiry date.
Do not use DEVIT-3 after the expiry date, which is stated on packaging/cardboard box/bottle. Use before expiry date.

If you notice defects on the product and/or its packaging, do not use DEVIT-3.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

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