PACKAGE LEAFLET: INFORMATION FOR THE USER

DEVIT-3 300.000 IU/ml Solution for IM Injection
For intramuscular administration.
Sterile

Active substance: Each 1 ml ampoule contains 7.5 mg (300.000 IU) vitamin D_3 (obtained from lanolin from sheep wool)
Excipients: Butylated hydroxytoluene, 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 is a light yellow-colored, oily solution with characteristic odor in colored 1 ml ampoules. Each box contains 1, 50 or 100 ampoules of 1 ml. Each 1 ml ampoule contains vitamin D_3 as drug substance. Vitamin D is obtained from lanolin from sheep wool.
- DEVIT-3 contains vitamin D3 which is a hormone regulating the calcium and phosphate metabolism.
- DEVIT-3 is indicated for Vitamin D deficiency in only patients with gastrointestinal tract absorption disorders.

2. BEFORE YOU TAKE DEVIT-3

DO NOT use DEVIT-3
- if you are allergic to cholecalciferol or any of the other ingredients of this medicine
- in case of hypercalcemia (increased calcium concentration in blood) and/or
- in case of hypercalciuria (increased calcium concentration in urine);
- during pregnancy and lactation.

TAKE SPECIAL CARE with DEVIT-3
DEVIT-3 should not be administered to you,
- If you tend to form kidney stones containing calcium (if your doctor has suspicions) or if you had kidney stones before

- If you suffer from hereditary dysfunction of the excretion of phosphate (pseudohypoparathyroidism). The demand of vitamin D can be reduced due to the temporarily normal vitamin D sensitivity with a risk of a long-lasting overdose. In this case easily controllable vitamin D derivatives are available;

Take special care with DEVIT-3,
- If your kidney excretion of calcium and phosphate is impaired (in these patients the effect on the calcium and phosphate level should be monitored); if your mobility is reduced (e.g. due to a cast); if you are treated with derivatives of benzothiadiazine (diuretic drugs). In these cases, there is a risk of increased calcium concentration in the blood (hypercalcemia) and increased calcium concentration in the urine (hypercalciuria). Calcium levels in blood and urine must be monitored.
- If you suffer from sarcoidosis (Boeck's disease), because the risk of transformation of vitamin D into its active metabolites is increased. The calcium levels in blood and urine should be monitored in these patients.
- 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.

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.

During long-term therapy with DEVIT-3 the calcium levels in blood and urine should be monitored every 3 to 6 months, and the kidney function should be checked by measuring the serum creatinine. This check is particularly important in older patients and during simultaneous therapy with cardiac glycosides (drugs to increase the contraction force of the cardiac muscle) or diuretics (diuretic drugs). In case of hypercalcemia (increased calcium concentration in blood) or symptoms of impaired kidney function the dosage must be reduced or the therapy must be stopped. It is recommended to reduce the dosage or to interrupt the therapy, if the calcium level in the urine exceeds 7.5 mmol/24 hours (300 mg/24 hours).

If other drugs containing vitamin D are administered, the dosage of vitamin D from DEVIT-3 must be taken into account. Additional administration of vitamin D or calcium should only be carried out under a medical supervision. In such cases the calcium levels in blood and urine must be monitored.

In patients with kidney impairment treated with DEVIT-3, the effect on the calcium and phosphate balance should be monitored.

If these warnings are valid for you, even if for a period in the past, please consult to 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.
DEVIT-3 should not be used during pregnancy.
Overdose of vitamin D in pregnancy must be prevented since long-lasting hypercalcemia (increased calcium concentration in blood) can lead to physical and mental retardation as well as to congenital heart and eye diseases of the child. If a vitamin D supplement should be required a drug with a

lower cholecalciferol content than DEVIT-3 should be chosen.

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.

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

Breast-feeding
DEVIT-3 should not be used during lactation. If a vitamin D supplement should be required a drug with a lower cholecalciferol content than DEVIT-3 should be chosen.
There is a risk of hypercalcemia (increased calcium in the blood) in infants of mothers who use therapeutic doses of Vitamin D.

Consult your doctor or pharmacist before taking this medicine.

Driving and using machines
No effects are known to this day.

Important information about some inactive ingredients of DEVIT-3
Warning is not required for any of the excipients in its composition.

Taking other medicines
DEVIT-3 is influenced as follows:
Phenytoin (drugs for treatment of epilepsy) or barbiturates (drugs for treatment of epilepsy and sleep disorders or for anesthesia) can reduce the effect of Vitamin D3.
Thiazide diuretics (diuretic drugs) can lead to hypercalcemia (increased calcium concentration in blood). Therefore, the calcium level in blood and urine should be monitored during a long-term therapy.
The simultaneous administration of glucocorticoids (drugs for treatment of certain allergic diseases) can reduce the effect of vitamin D3.

DEVIT-3 influences the effects of the following drugs:
The risk of side effects during treatment with cardiac glycosides (drugs to increase the contraction force of the cardiac muscle) may be raised due to an increase of the calcium level in blood while taking vitamin D (risk of cardiac dysrhythmia). In these patients ECG and calcium level in blood and urine should be monitored.
Only in exceptional cases and under serum calcium checks DEVIT-3 should be combined with metabolic products or analogues of vitamin D.

Please inform 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 it exactly as your doctor has told you. 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.

Dose and duration of treatment are determined on doctor's advice according to the disease to be treated.
Your doctor will tell you how frequently you will use DEVIT-3. Depending on your response to treatment, your doctor may recommend a higher or lower dose.
Do not exceed the recommended dose.

Route and method of administration:
DEVIT-3 is administered via intramuscular route. It must be injected into the muscle in calcium malabsorption.

Different age groups

Use in children
It is used as indicated in the section above.

Use in the elderly
No data.

Use in special conditions

Use in Kidney 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.

Use in Liver Failure
No data.

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

Symptoms of overdose
Overdose leads to an increase of phosphorus in blood and urine and to the hypercalcemia syndrome (increased calcium concentration in blood), later also to calcium deposit in the tissues, primarily in the kidneys (nephrolithiasis, nephrocalcinosis) and the vessels.
The symptoms of an intoxication are nonspecific and may appear as nausea, vomiting, at first often as diarrhea, later on as obstipation, anorexia (loss of appetite), weakness, headache, muscle and joint pain, muscle weakness as well as persistent drowsiness, azotemia (increased nitrogen concentration in blood), polydipsia (excessive thirst) and polyuria (increased urge to urinate), finally as exsiccosis (dehydration). Typical laboratory test results are hypercalcemia (increased calcium concentration in blood), hypercalciuria (increased calcium concentration in urine) as well as increased serum levels of 25-hydroxycalciferol.

Treatment of overdose
In case of an overdose measures for the treatment of the often long lasting and potentially threatening hypercalcemia (increased calcium concentration in blood) are required.
The first measure is to stop the administration of the vitamin D product; a normalization of the hypercalcemia due to vitamin D intoxication lasts for several weeks.
Graduated according to the extent of the hypercalcemia calcium low or calcium free nutrition, plenty intake of fluids, forced diuresis by means of the drug furosemide as well as the administration of glucocorticoids (drugs for treatment of certain allergic diseases) and calcitonine (hormone regulating the calcium concentration in the blood) may be applied.
Infusions of isotonic saline solution (3-6 l in 24 hours) with addition of furosemide (drug to increase diuresis) as well as possibly 15 mg/kg BW/h sodium edetate (drug binding calcium in the blood) under continuous calcium and ECG-control have a quite reliable calcium lowering effect in patients with sufficient kidney function. Hemodialysis (blood purification) with calcium free dialysis fluid is indicated in case of oliguria (low output of urine).
A specific antidote does not exist.

If you forget to take DEVIT-3
If you assume that the previous application has been forgotten inform your doctor or pharmacist.
Do not take a double dose to make up for a forgotten dose.

If you stop using DEVIT-3
In case of an interruption or premature termination of the treatment your discomfort may worsen again or reappear. Please ask your doctor on this! Unless indicated by your doctor, do not stop treatment with 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, this medicine can cause side effects, although not everybody gets them.

Stop taking DEVIT-3, tell your doctor IMMEDIATELY or go to the nearest hospital emergency department if you notice any of the following side effects:

- Hypersensitivity symptoms such as itching, rash, hives (urticaria)

These are all very serious side effects. If you have any of these, this means you are severely allergic to DEVIT-3. You may need urgent medical treatment or hospitalization.

Side effects are classified in the following frequencies:

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.

- Increased levels of calcium in the urine (hypercalciuria), increased levels of calcium in the blood (hypercalcemia): These are detected with blood and urine tests.
- Psychic symptoms, impaired consciousness
- Irregular heartbeat (arrhythmia)
- Nausea, lack of appetite, weight loss
- Increase in the amount of urine (polyuria), lack of urination (anuria), excessive thirst (polydipsia), kidney stone formation, calcification of the kidney due to high levels of calcium in the blood (nephrocalcinosis), unusual calcification (extraosseous calcifications).

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 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/ampoule.

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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