PACKAGE LEAFLET

DEVIT-3 200,000 IU/10 ml Oral Drops, Solution
Taken by mouth.

- ***Active substance:*** Each 1 ml drop contains 0.5 mg (20,000 IU) cholecalciferol (derived from sheep wool fat).
- ***Excipients:*** Butylhydroxyanisole, refined sunflower oil.

Read all of this LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you visit a doctor or hospital while using this medicine, tell them that you are using this medicine.*
- *Please follow the instructions in this leaflet. Do not use any **higher** or **lower** doses than the recommended dose of this medicine.*

This leaflet includes:

1. What DEVIT-3 is and what it is used for
- DEVIT-3 contains the active substance cholecalciferol (vitamin D_3). Cholecalciferol is derived from sheep wool fat.
- DEVIT-3 is offered in a glass bottle with a dropper containing 10 ml solution, in a cardboard box.
- DEVIT-3 contains vitamin D_3, a hormone that regulates calcium and phosphate metabolism.

DEVIT-3 is used for the prevention, treatment and maintenance therapy of vitamin D deficiency.

2. What you need to know before you use DEVIT-3
DO NOT take DEVIT-3 in the following conditions
- If you are allergic (hypersensitive) to cholecalciferol (vitamin D_3) or any of the excipients (listed under the heading of PACKAGE LEAFLET)
- If you have severe hardening of the arteries (arteriosclerosis)
- If you suffer from hypervitaminosis D (a disease caused by excessive intake or accumulation of vitamin D; symptoms include loss of appetite, constipation, blurred vision and muscle weakness.)
- If you suffer from hypercalcemia (a higher than normal blood calcium concentration) or hypercalciuria (increased calcium excretion in urine)
- If you have kidney stones (calcium-containing) or severe kidney failure
- If you are sensitive to calcium

Use DEVIT-3 with SPECIAL CARE in the following conditions
- If you are bedridden or inactive (e.g. if you have a condition that limits your mobility, such as a cast)

- If you are using benzothiadiazine-derived diuretics (water pills)
- If you are being treated with certain heart medications (cardiac glycosides)
- If you have a history of kidney stones
- If you have sarcoidosis (Boeck's disease); there is a risk of increased levels of the active form of vitamin D.
- If you have pseudohypoparathyroidism (a type of parathyroid gland failure)
- If you have kidney dysfunction. Your doctor will monitor the calcium and phosphate levels in the blood in this case. The risk of soft tissue calcification has to be considered.
- If you are using another medicine containing vitamin D and its derivatives. Avoid the use of other vitamin D-containing products at the same time, especially in babies.
- If you have elevated levels of parathyroid hormone, which can increase the metabolism of vitamin D and thus the need for vitamin D
- If your bone mass is reduced due to inactivity (e.g. bed rest); there is an increased risk of occurrence of elevated calcium levels in the blood.

Although the routine use of vitamin D-containing medicines is not recommended during pregnancy, they should be used under the supervision of a physician when necessary.

When using vitamin D-containing medicines for preventive therapy during pregnancy, the maximum daily dose should not exceed 1,000 IU.

The therapeutic index of vitamin D is quite low in babies and children. Hypercalcemia causes mental and physical retardation in babies if it persists. There is a risk of hypercalcemia in babies of breastfeeding mothers taking pharmacological doses of vitamin D.

The highest tolerated dose for long-term treatment and preventive therapy in risk groups is 4,000 IU/day (100 mcg/day) for children over 11 years of age and adults.

If any of these warnings apply to you, even at any time in the past, please consult your doctor.

Taking DEVIT-3 with food and drink
There are no known interactions with food or drinks. Caution is advised concerning vitamin-enriched food or infant formula.

Pregnancy
Ask your doctor or pharmacist before using this medicine.

Although the routine use of vitamin D-containing medicines is not recommended during pregnancy, they should be used under the supervision of a physician when necessary.

When using vitamin D-containing medicines for preventive treatment during pregnancy, the maximum daily dose should not exceed 1,000 IU.

If your doctor has prescribed DEVIT-3 during your pregnancy, make sure you strictly follow the dosage recommended by your doctor, as overdose of vitamin D_3 may put your child at risk of heart and eye diseases, as well as physical and mental retardation.

Talk to your doctor or pharmacist immediately if you find out that you are pregnant during the treatment.

Breastfeeding
Ask your doctor or pharmacist before using this medicine.

Vitamin D and its metabolites pass into breast milk. There is a risk of hypercalcemia (high levels of calcium in the blood) in babies of mothers taking remedial doses of vitamin D. This should be taken into account if the child receives additional vitamin D.

Driving and using machines
There is no information that DEVIT-3 affects the ability to drive and use machines.

Important information about some of the ingredients of DEVIT-3
It does not contain any excipients that require a warning.

Using with other medicines
The effects of vitamin D may decrease when used together with medicines for epilepsy treatment (carbamazepine, phenobarbital, phenytoin, primidone), or rifampicin or isoniazid (antibiotics used to treat tuberculosis).

When used with drugs containing high doses of calcium or with diuretics and thiazide diuretics (water pills), the concentration of calcium in the blood may rise above the normal level (risk of hypercalcemia). Careful monitoring of serum calcium concentrations is necessary during long-term treatment.

Certain hormones of the adrenal cortex (glucocorticoids, "cortisone") may reduce the effect of vitamin D.

It is not recommended to use it with other drugs containing vitamin D or its derivatives due to the increased possibility of poisoning (toxicity).

Actinomycin (anticancer medicine) and ketoconazole (antifungal medicine) may affect the metabolism of vitamin D.

Isoniazid (used to treat tuberculosis) may reduce the effectiveness of vitamin D_3.

Patients treated with cardiac glycosides (drugs used for heart failure, such as digoxin, etc.) may be sensitive to high calcium levels, and therefore the ECG (i.e. heart graph) parameters and calcium levels of these patients must be monitored by the doctor.

Medicines used to treat constipation and drugs that lower blood lipids (such as orlistat and cholestyramine) may reduce the absorption of vitamin D.

Medicines containing magnesium (e.g. antacids): They should not be used during DEVIT-3 treatment as this may lead to high magnesium levels in the blood (hypermagnesemia).

Pills containing aluminum (against heartburn): Vitamin D_3 may increase the absorption of aluminum from the gut.

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

3. How to use DEVIT-3

Instructions for proper use and dose/frequency of administration

Always take DEVIT-3 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Each ml of DEVIT-3 solution contains 25 drops. Each drop contains about 800 IU cholecalciferol.

Your doctor will decide the dose of the medicine. Follow your doctor's instructions.

Age Groups	Recommended Dosage for Prevention Treatment / Long-Term Treatment	Treatment Dosage for Vitamin D Deficiency		Maximum Tolerated Dose for Long-Term Treatment and Preventive Treatment of Risk Groups
		Daily Treatment**	Weekly Administration	
Newborn babies	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 1000 IU when necessary.*
*** Can be used for up to 6-8 weeks.*
**** If a weekly dose is preferred instead of daily, 50,000 IU can be used as a single dose for up to 6-8 weeks. Using more than 50,000 IU of vitamin D at a time is not recommended.*

Although the routine use of vitamin D-containing medicines is not recommended during pregnancy, they should be used under the supervision of a physician when necessary.

When using vitamin D-containing medicines for preventive therapy during pregnancy, the maximum daily dose should not exceed 1,000 IU.

Route and method of administration

DEVIT-3 is taken by mouth once a day.

For babies or people who cannot receive injections, it is preferable to take the medicine by mouth. The medicine can be given to babies by mixing it with food.

Different age groups

- **Use in children:**

The medicine should only be used if recommended by a doctor. It should be used as directed in the section “Instructions for proper use and dose/frequency of administration”.

- **Use in the elderly:**

No dose adjustment is needed.

Special conditions for use

- **Kidney failure:**

No dose adjustment is needed. In cases where vitamin D_3 must be taken continuously, kidney function should be monitored. It should not be used in case of severe kidney failure.

- **Liver failure:**

No data is available.

If you think that the effect of DEVIT-3 is too strong or too weak, consult your physician or pharmacist.

If you have used more DEVIT-3 than you should

If you take an overdose of DEVIT-3, you may develop hypercalcemia. Symptoms of hypercalcemia include tiredness, headache, psychiatric symptoms (such as euphoria [intense feelings of joy, confidence, and strength], dizziness, and confusion), nausea, vomiting, loss of appetite, weight loss, thirst, polyuria (excessive urination), kidney stone formation, excessive calcification in bones and kidney failure, ECG changes, heart rhythm disturbance and pancreatitis (inflammation of the pancreas).

Treatment: The doctor will determine the severity of poisoning and apply appropriate treatment.

Talk to a doctor or pharmacist if you have used more DEVIT-3 than you should.

If you forget to take DEVIT-3

Do not use a double dose to make up for the forgotten doses.

Possible effects when stopping to use DEVIT-3

No effects are expected when treatment is stopped. Do not stop the treatment with DEVIT-3 unless directed by your doctor.

4. Possible side effects

Like all other medicines, DEVIT-3 may cause side effects in people with hypersensitivity to its ingredients.

The frequency of side effects is unknown due to the lack of large-scale clinical trials.

Side effects are listed as shown in the categories below:

Very common	: may occur in at least 1 in 10 patients.
Common	: may occur in less than 1 in 10 but more than 1 in 100 patients.
Uncommon	: may occur in less than 1 in 100 but more than 1 in 1,000 patients.
Rare	: may occur in less than 1 in 1,000 but more than 1 in 10,000 patients.
Very rare	: may occur in less than 1 in 10,000 patients.
Not known	: may occur in too few patients to be estimated from the available data.

If you get any of the following symptoms, stop taking DEVIT-3 and IMMEDIATELY inform your doctor or go to the emergency department at your nearest hospital:

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

These are all very serious side effects. If you experience any of them, it means you are seriously allergic to DEVIT-3. You may need immediate medical intervention or hospitalization.

DEVIT-3 is unlikely to cause side effects at normal doses and duration. The following side effects may occur as a result of high doses of vitamin D_3 and uncontrolled prolongation of treatment:

Uncommon:
- High amount of calcium in blood (hypercalcemia). You may feel nausea or vomiting, loss of appetite, constipation, stomach pain, feeling very thirsty, muscle weakness, drowsiness, confusion.
- Increase in the amount of calcium in the urine (hypercalciuria)

Rare:
- Skin rash
- Itching
- Urticaria

Not known:
- Constipation
- Nausea
- Diarrhea
- Stomach pain
- Bloating

If you notice any side effects not listed in this leaflet, please inform 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 reach and sight of children, and in its original package.
Store at room temperature below 25°C, tightly closed, protected from light.

Use it in line with its expiry date.
Do not use DEVIT-3 after the expiry date stated on the package, cardboard box or bottle; use it before this date.

Do not use DEVIT-3 if you notice any defects in the product and/or its packaging.

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 / TÜRKİYE

Manufacturing site:
DEVA Holding A.Ş.
Kapaklı - TEKİRDAĞ / TÜRKİYE

This package leaflet was last revised on 23/11/2021.