PATIENT INFORMATION LEAFLET

TERA-D3 300.000 I.U./mL IM Ampule

Sterile

For intramuscular administration

- ***Active Ingredient:*** 2 mL ampule that containing 1 mL solution: It contains 7.5 mg (300.000 I.U.) Vitamin D3.
- ***Inactive Ingredients:*** Butylhydroxytoluene, sunflower oil.

Read all of this 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, please ask to your doctor or pharmacist.*
- *This medicine is prescribed only for you. Do not pass it on to others.*
- *If you visit a doctor or hospital during usage of this medicine, please give information to your doctor that you are taking this medicine.*
- *Please strictly follow instructions in this prescribing leaflet. Do not take **lower or higher** dose than recommended dose.*

What is in this leaflet:

1. What is TERA-D3 and what it is used for?

TERA-D3 is straw yellow oily solution with characteristic odor presented in 2 ml colored ampule. Each carton box contains 1 unit and 50 units of 2 mL ampule containing 1 mL solution. Each 2 mL ampule containing 1 mL solution contains Vitamin D3 as active ingredient

TERA-D3 is indicated only in patients with gastrointestinal absorption disorders in vitamin D deficiency.

2. What you need to know before you take TERA-D3

DO NOT TAKE TERA-D3 in following cases.

If you,

- have allergy to Vitamin D3 or any of the other inactive ingredients of TERA-D3, you shouldn't take this medicine.
- have severe high blood pressure (hypertension), severe arteriosclerosis and pneumonophthisis you shouldn't take this medicine for long terms with high dose.
- have hypervitaminosis D (a disease that occurs due to high intake or accumulation of Vitamin D. Symptoms; loss of appetite, constipation, blurred vision and muscle weakness)
- have hypercalcaemia (having high levels of calcium concentration in blood) or hypercalciuria (increase of calcium levels with urine),

TAKE SPECIAL CARE with TERA-D3 in following cases.

- If you need to take Vitamin D3 continuously, your kidney functions should be controlled.
- If you are using medicines that contain Vitamin D or derivatives.
- Although routine use of drugs containing vitamin D is not recommended during pregnancy, it should be used under the supervision of a physician when necessary.
- When using drugs containing vitamin D for prophylaxis during pregnancy, the maximum dose should not exceed 1000 IU / day.
- Please consult your doctor if these warnings are valid for you, even at any time in the past.

Taking TERA-D3 with food and drink

This medicine has no known interaction with foods and drinks.

Pregnancy

Consult your doctor before using this medication.

If you notice that you are pregnant during your treatment, immediately contact your doctor or pharmacist.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

Driving and using machines

There is no information that TERA-D3 affects ability of to drive or use any tools or machines.

Important information about some of the inactive ingredients of TERA-D3

There is no warning for any inactive ingredient contained in the medicine.

Taking other medicines

When used with anticonvulsants, hydantoin, barbiturate, primidon (used to treat epilepsy), rifampicin (used to treat tuberculosis) and glucocorticoids (like hormone medicines), efficiency of Vitamin D might be decreased.

When used in hypercalcemia (disease of having high blood calcium level) treatment with medicines containing calcitonin, etidronate, gallium nitrate, pamidronate or pliamisin, it might reduce efficiency of mentioned medicines.

When used with medicines with high calcium level or diuretic medicines, calcium level in blood might get higher than normal values (risk of hypercalcaemia). Serum calcium concentrations should be observed carefully in long-term treatments.

Taking Vitamin D or derivatives contains with other medicines, due to increase possibility of toxicity, it is not recommended.

Isoniazide (used to treat tuberculosis) might reduce efficiency of Vitamin D3.

Patients treated with cardiac glycosides (medicines used to treat heart failure) might be sensitive to high calcium levels and therefore EKG (electrocardiogram) parameters and calcium levels of these patients should observe by doctor.

Medicines that cause decrease of fat absorption, orlistat (used to treat obesity) and cholestiramine (used to treat cholesterol) might reduce absorption of Vitamin D.

If you are currently taking or have recently taken any prescription or non-prescription medicine, please give information to your doctor or pharmacist accordingly.

3. How to use TERA-D3?

Instructions for appropriate usage and dosing/administration frequency:

Your doctor will decide how to use the drug. Use according to your doctor's advice.

Age group	**Prophylaxis / Maintenance Recommended Dose**	**Vitamin D Deficiency Treatment Dose**		**Highest Tolerable Dose for Maintenance Treatment and Prophylaxis of Risky Groups**
		Daily Treatment**	**Weekly Practice**	
Newborn	400 IU/day (10µg/day)	1000 IU/ day (25µg/ day)	NONE	1000 IU/ day (25µg/ day)
1 months – 1 age	400 IU/gün (10µg/gün)	2000-3000 IU/ day (50-75 µg/ day)	NONE	1500 IU/ day (37.5 µg/ day)
1-10 age	400-800* IU/ day (10-20 µg/ day)	3000-5000 IU/ day (75-125 µg/ day)	NONE	2000 IU/day (50 µg/day)
11-18 age	400-800* IU/ day (10-20 µg/gün)	3000-5000 IU/ day (75-125 µg/ day)	NONE	4000 IU/ day (100 µg/ day)
Adults over the age of 18	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)

** It can increase to 1000 IU if necessary.*
***It can be used up to 6-8 weeks.*
**** If it is desired to apply a weekly dose instead of daily, 50.000 IU can be used as a weekly dose up to 6-8 weeks at a time.*

Administration Way and Method:

TERA-D3 Ampule is administered intramuscular.

Different age groups:

Use in Children:

Administration and dose/use frequency should be use as mentioned instructions section.

Use in Elderly:

No dose adjustment is necessary for elderly patients.

Special Uses:

Kidney/Liver Failure:

No dose adjustment is necessary. In cases where continuous Vitamin D3 administration is required, kidney functions should be controlled. It shouldn’t take together with calcium in case of severe kidney failure.

If you have impression for effect of the TERA-D3 *for being too strong or weak, consult to your doctor or pharmacist.*

If you take more TERA-D3 than you should:

If you took more TERA-D3 than your prescribed dose, contact a doctor or pharmacist.

If you forget to take TERA-D3:

If you forget to take a dose, take it as soon as you remember it; then take your next dose on its regular time. However, if it is almost time for your next dose, skip the missed dose.

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

Possible effects after completion of TERA-D3 treatment

No effect is likely to happen after completion of treatment. Do not stop TERA-D3 treatment unless asked by your doctor.

4. What are possible side effects?

Like all medicines, TERA-D3 can have side effects on persons who are sensitive to the materials in its content.

Since comprehensive clinical studies are not conducted, frequency of unwanted effects is not known.

Side effect possibility of TERA-D3 in normal doses and periods is low. If Vitamin D is administered in high doses and treatment period is extended out of control, following side effects might occur (frequency of the side effects are unknown):

Increase in calcium amount excreted by urination (hypercalcinuria), high level of calcium in blood (hypercalcaemia), high level of residual nitrogen in blood: These are detected with blood and urinary tests.

Mental symptoms, mental fog

Arrhythmia

Nausea, loss of appetite, loss of weight

Polyuria (excessive urination)

Anuria

Polydipsia (excessive thirst)

Formation of kidney stone

Nephrocalcinosis due to high calcium in blood

Hypersensitivity symptoms such as pruritus, rash, urticaria

If you get any side effects not listed in this leaflet, please give information to your doctor or pharmacist.

Reporting of Side Effects

If you get any side effects listed or not listed in this leaflet, please give information to your doctor, pharmacist or nurse. You can also report side effects directly to Turkish Pharmacovigilance Center (TÜFAM) by calling 0 800 314 00 08 or by clicking "Medicine Side Effect Notice" icon at www.titck.gov.tr. By reporting the occurred side effects, you can help provide more information on the safety of this medicine.

5. How to store TERA-D3?

Keep TERA-D3 out of sight and reach of children, and store in its package.

Store at room temperature below 25°C, in a dry place, away from light and keep in its packaging.

Use in accordance with the expiration date.

Do not use TERA-D3 after the expiry date, which is stated on the package.

If you notice any defects in the product and/or package, do not use TERA-D3.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanisation.

Marketing Authorisation Holder:

Terra İlaç ve Kimya San. ve Tic. A.Ş.

Ümraniye/İstanbul – Turkey

Manufacturer:

Turk İlaç ve Serum Sanayi A.Ş.

Akyurt/Ankara

This leaflet is approved on 15.01.2020

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Terra İlaç ve Kimya San. ve Tic. A.Ş.

Ümraniye/İstanbul – Turkey

Manufacturer:

My Farma İlaç San. ve Tic. A.Ş.

Tuzla /İstanbul

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