PATIENT INFORMATION LEAFLET

DESIFEROL 50.000 IU/15 ml oral drops
For oral use only

Active substance(s): Each bottle (15 ml) contains 50.000 I.U. vitamin D_3 (obtained from sheep wool).
Excipient(s): Butylhydroxyanisole and sunflower oil.

Read this PATIENT INFORMATION 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 only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. What DESIFEROL is and what it is used for?

- DESIFEROL contains cholecalciferol (vitamin D_3) as active substance (obtained from sheep wool)
- Its appearance is yellowish, clear, particle-free oily solution.
- DESIFEROL is marketed in amber colored glass bottles (Type III) closed with pilfer-proof HDPE closure and LDPE dropper seal in a cardboard box.
- DESIFEROL is used in the treatment, maintenance and prevention of vitamin D deficiency.

2. What you need to know before you use DESIFEROL?

DO NOT use DESIFEROL
If;

- you are allergic (hypersensitive) to cholecalciferol (vitamin D_3) or any of the excipients
- you have high blood pressure (hypertension)
- you have advanced arteriosclerosis
- you have active pulmonary tuberculosis (phthisis), then you should not use the drug for a long time at high dosages
- you have D hypervitaminosis (a disorder due to excessive intake or accumulation of vitamin D which has the symptoms of; anorexia, constipation, blurred vision and muscle weakness.)

- you have hypercalcemia (increased serum calcium concentration above normal levels) or hypercalciuria (increased amount of calcium excreted in the urine)
- you have nephrolithiasis (calciferous)
- You are hypersensitive to calcium

Warnings and precautions

The following patients are at high risk for vitamin D deficiency. The maximum tolerated dose to prevent vitamin D deficiency in these patients is given in the section "3. How to use DESIFEROL" and below, according to age groups.

- Patients requiring care or inpatient
- Patients with dark skin color
- People who are not sufficiently exposed to the sun or use sunscreen continuously
- Patients evaluated for osteoporosis
- Obese (overweight) patients
- Simultaneous use of some drugs (e.g. anticonvulsant drugs (drugs used in epilepsy), glucocorticoids (hormone-like drugs), anti-retrovirals (drugs used in virus treatment)
- Patients recently treated for vitamin D deficiency and require maintenance therapy
- Patients with liver or kidney disease
- Patients with malabsorption (absorption disorder in the intestine), inflammatory bowel disease, and celiac disease (an inflammatory bowel disease associated with sensitivity to wheat products)
- In support of the specific treatment of osteoporosis: 8 drops per day (1000 IU)

The maximum tolerated doses to prevent vitamin D deficiency in patients at high risk for vitamin D deficiency:

Age Group	Maximum Tolerated Dose (IU/day)	Maximum Tolerated Drops/day
Newborn	1000 IU/day (25 µg/day)	8 drops/day
1 month-1 year	1500 IU/day (37,5 µg/day)	11 drops /day
1-10 years	2000 IU/day (50 µg/day)	15 drops /day
11-18 years	4000 IU/day (100 µg/day)	30 drops /day
Adults over the age of 18	4000 IU/day (100 µg/day)	30 drops /day

Although routine use of drugs containing vitamin D is not recommended during pregnancy, it can be used under the supervision of a doctor if necessary.

The maximum dose should not exceed 1000 IU / day (8 drops per day) in the use of drugs containing vitamin D for the purpose of prophylaxis (prevention of vitamin D deficiency) in pregnancy.

Consult your doctor in the following conditions;

- If your mobility is restricted

- If you have been using diuretic agents of benzothiadiazine derivatives
- If you have a history of nephrolithiasis
- If you have sarcoidosis (is a benign disease that affects multiple organs in the body, but mostly the lungs and lymph glands)
- If you have pseudohypoparathyroidism (a kind of parathyroid gland disorder)
- If you have renal impairment
- If you have been on another medication that contains vitamin D or its derivatives

Vitamin D has a very low therapeutic index in infants and children. Hypercalcemia (high level of calcium in the blood) leads to mental and physical development retardation in infants in prolonged exposure. In therapeutic (pharmacologic) doses, infants to nursing mothers receiving vitamin D at pharmacologic dosage are at risk of hypercalcemia.

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

DESIFEROL with food and drink

No known interaction with food and drinks.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.

Although routine use of DESIFEROL is not recommended during pregnancy, it can be used under the control of a doctor if necessary.

In the use of drugs containing vitamin D for prevention during pregnancy, the maximum dose should not exceed 1000 IU / day.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding
Consult your doctor or pharmacist before taking this medicine.

Vitamin D passes into breast milk.

Driving and using machines
There are no data on the effects on the ability to drive and use machines.

Important information about some of the excipients of DESIFEROL
It does not contain any excipients that require a warning.

Other medicines and DESIFEROL

Concomitant use with anticonvulsant agents, hydantoin, barbiturates or pyrimydon (medications used in epilepsy), rifampicin (an antibiotic used to treat tuberculosis) may reduce the activity of vitamin D.

Concomitant use with medications containing calcitonin, etidronat, gallium nitrate, pamidronate or pliamycin in hypercalcemia (a disease characterized by high calcium levels in the blood) treatment may reduce the effectiveness of these medications.

Concomitant use with medications containing high doses of calcium or diuretics and thiazide diuretics calcium concentration in the blood may be elevated above normal level (hypercalcemia risk). Long term treatments require careful monitoring of serum calcium concentrations.

Concomitant use with other products containing vitamin D or derivatives of vitamin D is not recommended due to increased risk of toxicity.

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

Patients treated with cardiac glycosides (medications used in heart failure) may be susceptible to high calcium levels and therefore should have ECG (electrocardiography) parameters and calcium levels monitored under medical supervision.

Drugs that may reduce fat absorption like orlistat (used to treat obesity.) and cholestyramine (used to treat high cholesterol.) may reduce the absorption of vitamin D.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use DESIFEROL?

- **Instructions for use and dosage/frequency of administration:**

Your doctor will decide how to use DESIFEROL. Use according to your doctor's advice. Check with your doctor or pharmacist if you are not sure.

1 ml DESIFEROL consists of 25 drops.

Age Group	**Proposed Dose for Prevention / Maintenance**		**Treatment Dosage for Vitamin D Deficiency**			**Maximum Tolerated Dose for Maintenance and Prevention in Groups At Risk**	
			Daily treatment **		**Weekly treatment**		
Newborn	400 IU/day (10 μg/ day)	3 drops	1000 IU/ day (25 μg/ day)	8 drops	Not applicable	1000 IU/ day (25 μg/ day)	8 drops
1 month-1 year	400 IU/ day (10 μg/ day)	3 drops	2000-3000 IU/ day (50-75 μg/ day)	15 - 23 drops	Not applicable	1500 IU/ day (37.5 μg/ day)	11 drops
1-10 years	400-800* IU/day (10-20 μg/ day)	3-6 drops	3000-5000 IU/ day (75-125 μg/ day)	23 - 38 drops	Not applicable	2000 IU/ day (50 μg/ day)	15 drops
11-18 years	400-800* IU/day (10-20 μg/ day)	3-6 drops	3000-5000 IU/ day (75-125 μg/ day)	23 - 38 drops	Not applicable	4000 IU/ day (100 μg/ day)	30 drops
Adults over the age of 18	600-1500 IU/ day (15-37.5 μg/ day)	5-11 drops	7000-10.000 IU/ day (175-250 μg/ day)	53 - 75 drops	50.000 IU/week (1250 μg/week)***	4000 IU/ day (100 μg/ day)	30 drops

** If necessary, it can be increased up to 1000 IU.*

*** It can be used up to 6-8 weeks.*

**** If it is desired to apply a weekly dose instead of daily, the dose of 50,000 IU can be used as a weekly dose at a single time (1 bottle) up to 6-8 weeks. It is not recommended to use more than 50,000 IU of vitamin D at a time.*

Although routine use of drugs containing vitamin D is not recommended during pregnancy, it can be used under the control of a doctor if necessary.

In the use of drugs containing vitamin D for prevention during pregnancy, the maximum dose should not exceed 1000 IU / day.

- **Route of administration and method:**

DESIFEROL is used orally once a day.

For breast-fed infants or for those who are unable to receive injection, administration via oral route is preferred. It may be added to food in breast-fed infants.

- **Different age groups:**

Use in children:

Used as described in the section Instructions for use and dosage/frequency of administration.

Use in elderly:

No dose adjustment is required.

- **Special cases of use:**

Renal/Hepatic failure:

No dose adjustment is required. Chronic use of vitamin D_3 when required should be accompanied with routine controls of kidney functions. In severe renal failure, concomitant use with calcium should be avoided.

If you have the impression that the effect of DESIFEROL is very strong or weak, tell a doctor or pharmacist.

If you use more DESIFEROL than you should:

If you use more DESIFEROL than you should, tell your doctor or pharmacist.

If you use DESIFEROL in excess amounts, you may develop hypercalcemia. Symptoms of hypercalcemia include: fatigue, psychiatric symptoms (euphoria [a state of extreme joy, self-confidence, or mania] dizziness, confusion), nausea, vomiting, loss of appetite, loss of weight, increased thirst, polyurea (frequent urination), kidney stone formation, nephrocalcinosis (accumulation of salts in kidneys), excessive calcification of bones and kidney failure, ECG changes, cardiac arrhythmia, and pancreatitis (inflammation of the pancreas).

Treatment: avoid exposure to sunlight. If the drug has recently ingested perform gastric lavage.

If you forget to use DESIFEROL:

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

If you stop using DESIFEROL:

Discontinuation of the treatment is not expected to cause any side effects. Unless otherwise told by your doctor, do not discontinue treatment with DESIFEROL.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Frequencies of adverse reactions are not known, as no larger clinical trials have been conducted.

DESIFEROL is less likely to have side effects at normal doses and times. The following side effects may develop as a result of high doses of vitamin D3 and uncontrolled prolongation of treatment:

If you notice any of the followings stop taking {name of the medicine} and immediately inform your doctor or go to the nearest emergency department

- Hypersensitivity symptoms such as itching, rash, white or reddish weals on the skin (urticaria).

These are all very serious side effects. If you have one of these, you have a serious allergy to DESIREROL. You may need an emergency medical intervention or hospitalization.

Side effects were listed by frequency as following:
Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

If you notice any of the followings immediately inform your doctor or go to the nearest emergency department

Not known:

- Increased amount of calcium excreted in the urine, amount of calcium in the blood higher than normal (hypercalcemia) and increased level of residual nitrogen in the blood (all of these parameters established through blood and urine tests.).
- Constipation, flatulence, nausea, abdominal pain, diarrhea.
- Excessive urination (polyuria), excessive thirst (polydipsia), being unable to void (anuria)
- Fever

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store DESIFEROL

Keep this medicine out of the sight and reach of children in its original packaging.
Store at room temperature below 25°C, tightly closed and away from light.

Use in accordance with expiry date

Do not use this medicine after the expiry date which is stated on the package/box/bottle.

Do not use this medicine if you notice any damage to the product and/or package.

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