

PATIENT INFORMATION LEAFLET

DESİFEROL PLUS 2000 IU+3333 IU+70 mg/ml oral drops, solution

For oral use only.

- **Active substance(s):** Each 1 ml oral drop (30 drops) contains 2000 IU of vitamin A palmitate, 3333 IU of vitamin D3 (obtained from sheep wool) and 70 mg of vitamin C.
- **Excipient(s):** Potassium sorbate, PEG 40 hydrogenated castor oil, glycerin, sucralose, povidone K90, sodium bicarbonate, sodium chloride, disodium EDTA, orange flavor and purified water.

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 DESİFEROL PLUS is and what it is used for?**
2. **What you need to know before you use DESİFEROL PLUS?**
3. **How to use DESİFEROL PLUS?**
4. **Possible side effects**
5. **How to store DESİFEROL PLUS?**

1. What DESİFEROL PLUS is and what it is used for?

- DESİFEROL PLUS is an oral drop containing vitamins A, D (obtained from sheep wool) and C. It is presented in a glass dropper bottle.
- DESİFEROL PLUS is presented in bottles containing 20 ml, 30 ml and 45 ml solution.
- DESİFEROL PLUS is used in patients with simultaneous vitamin A, D and C deficiency.

2. What you need to know before you use DESİFEROL PLUS?

DO NOT use DESİFEROL PLUS

- If you have an allergy (hypersensitivity) to any of the ingredients in its composition
- If you have severe high blood pressure (hypertension)
- If you have advanced arteriosclerosis
- If you have active pulmonary tuberculosis
- If there is hypervitaminosis A and D (a disorder due to excessive intake or accumulation of vitamin D which has the symptoms of; loss of appetite, constipation, blurred vision and muscle weakness)

- If you have hypercalcemia (increased serum calcium concentration above normal levels) or hypercalciuria (increase in the amount of calcium excreted in the urine)
- If you have kidney stones (containing calcium)
- If you are sensitive to calcium
- If you have kidney stones accompanied by acidic urine (Aciduria) or a normal urine pH but having oxalic acid in the urine.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Warnings and precautions

- If your mobility is restricted
- If you have been using diuretic agents of benzothiadiazine derivatives
- If you have impaired kidney function or a history of kidney stones
- If you have sarcoidosis (a chronic, granulomatous disease that can affect all tissues and organs (an inherited disease in which certain microorganisms cannot be killed by a type of white blood cell))
- If you have pseudohypoparathyroidism (a kind of parathyroid gland disorder)
- If you have a deficiency of the G6PD (glucose-6-phosphate dehydrogenase) enzyme (this is the deficiency or inactivity of an enzyme that is vital in blood sugar metabolism)
- If you have various types of anemia (mediterranean anemia, sideroblastic anemia, sickle cell anemia), if you have iron accumulation in your major organs, especially in the liver (hemochromatosis), if the amount of red blood cells in your blood has increased (polycythemia) or if you have leukemia (cancer of blood cells)
- If you have heart or lung disease
- If you have diabetes (Vitamin C may cause inaccuracies in urine sugar test results. Vitamin C use should be discontinued a few days before the test.)
- If you have advanced cancer
- If you have liver disease
- If you are using another drug containing vitamin D and its derivatives
- If you have inflammation in the gastrointestinal tract (enteritis, colitis, diverticulitis and ulcerative colitis)
- If you have pancreatic inflammation (pancreatitis) and stomach ulcer (peptic ulcer)
- If you have liver disease such as cirrhosis or liver inflammation due to viral infection
- If you have chronic kidney failure
- If you are sensitive to vitamin A

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.

High doses or long-term use of vitamin A can cause bleeding in the gums, dry mouth or sensitivity in the mouth, dryness, cracking or peeling of the lips.

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

DESİFEROL PLUS with food and drink:

Vitamin C in the content of this product can increase the absorption of iron.

No known interaction with food and drinks.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

There is insufficient information about the use of DESÍFEROL PLUS in pregnant women.

Animal studies are insufficient with respect to pregnancy / and-or / embryonal / fetal growth / and-or /natal / and-or / postnatal development. Potential risk is not known for human.

DESÍFEROL PLUS should not be used during pregnancy unless necessary.

The use of vitamins A, D and C in doses higher than the recommended daily dose during pregnancy should be avoided and should not be used without consulting a doctor.

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.

Since DESÍFEROL PLUS passes into milk during breastfeeding, it should not be used without consulting a doctor.

Driving and using machines

There is no information that it affects the ability to drive and use machines.

Important information about some of the excipients of DESÍFEROL PLUS

PEG 40 may cause nausea and diarrhea as it contains hydrogenated castor oil.

Other medicines and DESÍFEROL PLUS

The following drugs may interact with the vitamin A in DESÍFEROL PLUS:

- Medicines containing calcium
- Cholestyramine and colespolol (used to lower cholesterol in those with high cholesterol), mineral oil, orally taken neomycin (antibiotic used for local infection in the digestive tract)
- Birth control pills
- Medicines used in the treatment of skin diseases such as etretinate, isotretinoin
- Tetracycline used as an antibiotic
- Vitamin E

The following drugs may interact with the vitamin D in DESÍFEROL PLUS:

Vitamin D may interact with antacids containing aluminum and magnesium.

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.

Mineral oils may reduce the effect of vitamin D by reducing its absorption.

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, calcium concentration in the blood may be elevated above normal level (risk of hypercalcemia).

Long term treatments require careful monitoring of serum calcium concentrations.

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

Isoniazid (used to treat tuberculosis) may reduce the activity of vitamin D₃.

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.

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

Vitamin D may interact with drugs containing high doses of phosphorus.

The following drugs may interact with the vitamin C in DESİFEROL PLUS:

- Birth control pills
- Oral anticoagulants such as warfarin and dicumarol
- Iron drugs used in the treatment of anemia
- Desferrioxamine (a medicine used to treat iron overload disease)
- Isoprenaline (a drug that stimulates the sympathetic nervous system)
- Mexiletine (a medicine used against heart rhythm disorder)
- Barbiturates such as primidone (sedative and sleep-inducing drug or drug group)
- Amphetamine (a drug that stimulates the sympathetic nervous system)
- Tricyclic antidepressants (a group of drugs effective against mental depression)
- Fluphenazine and other phenothiazines (drug or drug group used in the treatment of psychiatric diseases such as schizophrenia and psychotic depression)
- Acetylsalicylic acid
- Medicines used to treat epilepsy (e.g. phenytoin)
- Tetracycline, an antibiotic
- Appetite suppressants

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 DESİFEROL PLUS?

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

1 ml of DESİFEROL PLUS is 30 drops.

Unless recommended otherwise by your doctor, the daily dose is determined in accordance with the table below:

Age Group	Number of drops daily	Vitamin D ₃ (IU)	Vitamin A (microgram)	Vitamin C (mg)
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6 months – 1 year	20 drops	2222 IU	400 micrograms	46 mg
1 – 3 years	30 drops	3333 IU	600 micrograms	69 mg
4 – 12 years	45 drops	5000 IU	900 micrograms	103 mg

One drop of DESÍFEROL PLUS contains 111.1 IU of Vitamin D3, 20 micrograms of Vitamin A, and 2.3 mg of Vitamin C.

- **Route of administration and method:**

DESÍFEROL is used orally.

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:

It is used as described in the section Instructions for use and dosage/frequency of administration.

It is not recommended for use in children under 6 months and over 12 years of age.

Use in elderly:

No dose adjustment is required.

- **Special cases of use**

Renal/Hepatic failure:

No dose adjustment is required. Chronic use of vitamin D3 when required should be accompanied with routine controls of kidney functions. In severe renal failure, concomitant use with calcium should be avoided.

Pediatric population:

It is used as described in the section Instructions for use and dosage/frequency of administration.

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

If you use more DESÍFEROL PLUS than you should:

If vitamins A and D are used in high doses for a long time, it causes hypervitaminosis (vitamin excess).

High doses of Vitamin C can cause gastrointestinal disorders, including diarrhea. High doses can also cause hyperoxaluria (more than normal oxalic acid in the urine) and kidney stone formation if the urine is acidic. Doses of 600 mg or more per day have a diuretic effect. In case of overdose, treatment should be stopped and symptomatic therapy should be carried out.

Symptoms of hypercalcemia are fatigue, psychiatric symptoms (e.g. euphoria (excessive emotions such as extreme joy, self-confidence, megalomania), drowsiness, confusion, etc.), nausea, vomiting, loss of appetite, loss of weight, increased thirst, constipation after diarrhea in the early period, abdominal pain, headache, muscle and joint pain, muscle weakness, polyuria (excessive urination), kidney stone formation, nephrocalcinosis (deposition of salt in the kidney), excessive calcification in bones and kidney failure, soft tissue calcification (accumulation of minerals in soft tissue instead of bone), ECG (recording of the electrical activity of the heart) changes, heart rhythm disorder and pancreatitis (inflammation of the pancreas).

In case of overdose due to vitamins A and C, treatment should be stopped and symptomatic and supportive treatment should be performed.

In cases of poisoning caused by vitamin D analogues, vitamin D administration is terminated, a low-calcium diet is applied, and intravenous (i.v.) fluids are administered. Calcium levels are lowered in the blood by using diuretics (such as furosemide and ethacrynic acid) when necessary.

If vitamin D has recently ingested, gastric lavage (gastric lavage) or emesis can be performed to prevent further absorption.

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

If you forget to use DESİFEROL PLUS:

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

Skip the missed dose and take the next dose at the usual time.

If you stop using DESİFEROL PLUS:

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

4. Possible side effects?

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

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.

Frequencies of side effects are not known, as no larger clinical trials have been conducted.

DESİFEROL PLUS 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 A, D3 and C and uncontrolled prolongation of treatment:

If you notice any of the followings stop taking DESİFEROL PLUS and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Allergic reactions such as rash, itching, difficulty in breathing, tightness in the chest, swelling of the mouth, face, lips and tongue
- Formation of kidney stones, hyperoxaluria (excessive amount of oxalate in the urine), difficulty in urination, diuresis (increase in urinary excretion rate, hence its volume)

These are all very serious side effects. You may need an emergency medical intervention or hospitalization.

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

Side effects from vitamin A

Very rare

- Menstrual disorders (menstrual irregularity)

Not known

- Headache
- Dizziness
- Nausea, vomiting
- Weakness
- Bulging fontanelle in infants (Munroe-Kietz syndrome)
- Increase in intracranial pressure in adults in the form of benign intracranial hypertension called brain pseudotumor
- Nose bleeding
- Blood clotting disorder (hypoprothrombinemia)
- Tiredness
- Drowsiness
- Sleeping disorders
- Psychic (mental) disorders
- Increased restlessness (Hyperirritability)
- Loss of appetite
- Pupil edema (papilla edema), double vision
- Enlargement of the liver and, more rarely, spleen
- Shedding of epithelial tissues, itching, hair loss, dry skin, cracked lips
- Bone and joint pain, thickening of the bone structure, cessation of growth in children (premature closure of the epiphysis)

Side effects from vitamin D

Uncommon

- Feeling of fullness
- Flushing or redness

Rare

- Signs of hypersensitivity such as itching, rash, white or reddish blisters on the skin (urticaria)

Very rare

- Local skin reactions

Unknown

- An increase in the amount of calcium excreted in the urine, a higher than normal amount of calcium in the blood (hypercalcemia) and an increase in the amount of residual (residual) nitrogen in the blood (These are detected by blood and urine tests)
- Psychological symptoms, clouding of consciousness
- Disturbance in heart beat rhythm (arrhythmias)
- Constipation, flatulence, nausea, abdominal pain, diarrhea, loss of appetite, loss of weight

- Excessive urination (polyuria), excessive thirst (polydipsia), inability to urinate (anuria), formation of kidney stones (nephrocalcinosis)
- Fever

Side effects from vitamin C

Rare

- Tenderness, pain, fever or swelling in the arms and legs

Not known

- Headache, dizziness or lightheadedness, tiredness, sleep disturbance
- Stomach cramps, diarrhea, nausea or vomiting
- Flushing or redness

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

5. How to store DESİFEROL PLUS?

*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.

Marketing Authorization Holder:

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