

## PATIENT INFORMATION LEAFLET

### DESÍFEROL 2000 IU film coated tablets

For oral use only.

- **Active substance(s):** Each 1 film coated tablet contains 2000 IU (50 micrograms) vitamin D<sub>3</sub> (obtained from sheep wool).
- **Excipient(s):**  
*Tablet:* Microcrystalline cellulose, calcium phosphate dibasic anhydrous (E341), lactose monohydrate (obtained from cow milk), povidone, croscopovidone, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate.  
*Coating material (SheffCoat Brilliant Silver 30712206):* Hydroxypropyl methyl cellulose, hypromellose type 2910, talc, triacetin, glycerol triacetate and mica based pearlescent pigment (titanium dioxide / mica)

**Read all of this PATIENT INFORMATION 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 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 DESÍFEROL is and what it is used for?*
2. *What you need to know before you use DESÍFEROL?*
3. *How to use DESÍFEROL?*
4. *Possible side effects*
5. *How to store DESÍFEROL?*

#### 1. What DESÍFEROL is and what it is used for?

- DESÍFEROL contains vitamin D<sub>3</sub> (obtained from sheep's wool). It is available in a package consisting of 40 and 60 film-coated tablets of pearlescent whitish color, shiny, round, notched on one side (in order to be divided into two equal doses).
- DESÍFEROL contains vitamin D<sub>3</sub>, which regulates calcium intake and metabolism and supports calcium incorporation into bone tissue.
- DESÍFEROL is used in the treatment of vitamin D deficiency, to continue the treatment of vitamin D deficiency (maintenance) and to prevent deficiency.

#### 2. What you need to know before you use DESÍFEROL?

##### **DO NOT use DESÍFEROL**

If;

- If you are allergic (hypersensitive) to cholecalciferol (vitamin D<sub>3</sub>) or any of the excipients
- If you have hypercalcemia (high amount of calcium in the blood) or hypercalciuria (high amount of calcium in the urine) or if you have a disease that can result in hypercalcemia and hypercalciuria
- If you have hypervitaminosis D (high amount of vitamin D in the blood)

- If you have kidney stones (nephrolithiasis) or kidney calcification (nephrocalcinosis)
- If you have severe kidney failure
- If you are under the age of 12

If any of the above apply to you, talk to your doctor or pharmacist before using DESIFEROL.

### **Warnings and precautions**

If;

- If you have heart disease or narrowing of your arteries
- If you have sarcoidosis (a specific connective tissue disease that can affect the lungs, skin, joints)
- If you are taking medications containing vitamin D
- If you have moderate to mild kidney problems.

Your doctor may ask you to have regular blood tests to check the level of calcium in your blood.

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

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

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

### **In children**

DESIFEROL is not recommended in children under 12 years of age.

### **DESIFEROL with food and drink**

You can use it with or without food.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

If you are pregnant, may be pregnant or are considering becoming pregnant, consult your doctor or pharmacist before using this medicine. Do not use DESIFEROL without consulting your doctor because taking too much vitamin D can harm your baby.

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

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

*If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

DESIFEROL can be used while breastfeeding. Vitamin D3 passes into breast milk. Supplemental vitamin D intake to the breastfed child should be considered in this situation.

There is a risk of increased blood calcium levels (hypercalcemia) in infants of breastfeeding mothers who receive therapeutic doses of vitamin D.

*If you are breastfeeding, consult your doctor or pharmacist before using this medicine.*

### **Driving and using machines**

DESIFEROL has no known effects on the ability to drive and use machines.

### **Important information about some of the excipients of DESIFEROL**

Since it contains lactose, if you have previously been told that you were intolerant to certain kinds of sugar contact to your doctor before using DESIFEROL.

### **Other medicines and DESIFEROL**

In particular, tell your doctor or pharmacist if you are taking any of the following, have recently taken or are using any other medicines.

- Medicines used in epilepsy such as barbiturates or other anticonvulsants (eg carbamazepine, phenobarbital, phenytoin, primidone) may reduce the effectiveness of vitamin D.
- Cholestyramine (used to treat high cholesterol) may cause decreased absorption of vitamin D,
- Phenytoin or barbiturates (drugs used in epilepsy)
- Lactacids (laxatives) containing paraffin oil
- Thiazide diuretics (medicines used to treat high blood pressure) reduce urinary calcium excretion and may increase the risk of hypercalcemia.
- Glucocorticosteroids (used in the treatment of inflammation) can reduce the effects of vitamin D.
- Cardiac glycosides (medicines to control your heart rate) eg digoxin. Your doctor can monitor your heart with an electrocardiogram (ECG) and measure calcium levels in your blood.
- Drugs used in the treatment of tuberculosis such as rifampicin, isoniazid
- Actinomycin (used in chemotherapy)
- Imidazole, ketoconazole, itraconazole (used in fungal treatment)
- Orlistat (used for weight loss) may reduce vitamin D absorption.
- Medicines containing vitamin D, calcium supplements
- Drugs that cause reduced fat absorption, such as colestipol (used to lower cholesterol), may cause decreased absorption of vitamin D.
- Phosphate infusion should not be administered due to the danger of metastatic calcification (precipitation of calcium salts in normal tissue due to hypercalcemia or hyperphosphatemia) in case of low hypercalcemia of hypervitaminosis 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:**

Each one film coated tablet contains 2000 IU (50 micrograms) Vitamin D<sub>3</sub>. The tablets can be divided into two equal doses, thanks to the notch, and a dose of 1000 IU (25 micrograms) can be adjusted.

Always take DESIFEROL as recommended by your doctor. If you are not sure about the use of the drug, consult your doctor or pharmacist.

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

Age Group	Recommended Dose for Prophylaxis / Maintenance Treatment	Treatment Dose for Vitamin D Deficiency		Maximum Tolerated Dose for Maintenance Treatment and Prophylaxis of Groups at Risk
		Daily treatment**	Weekly treatment***	
<b>New born</b>	400 IU/day (10 mcg/day)	1000 IU/day (25 mcg/day)	Not applicable	1000 IU/day (25 mcg/day)
<b>1 month – 1 year old</b>	400 IU/day (10 mcg/day)	2000-3000 IU/day (50-75 mcg/day)	Not applicable	1500 IU/day (37,5 mcg/day)
<b>1-10 years old</b>	400-800* IU/day (10-20 mcg/day)	3000-5000 IU/day (75-125 mcg/day)	Not applicable	2000 IU/day (50 mcg/day)
<b>11-18 years old</b>	400-800* IU/day (10-20 mcg/day)	3000-5000 IU/day (75-125 mcg/day)	Not applicable	4000 IU/day (100 mcg/day)
<b>Over 18 years old</b>	600-1500 IU/day (15-37,5 mcg/day)	7000-10.000 IU/day (175-250 mcg/day)	50.000 IU/week (1250 mcg/week)***	4000 IU/day (100 mcg/day)

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

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

\*\*\* If weekly dose is intended to be applied instead of daily dose, 50.000 IU can be used weekly up to 6-8 weeks. It is not recommended to use more than 50,000 IU of vitamin D at one time.

Although routine use is not recommended during pregnancy, it can be used under physician control, if necessary.

Maximum dose should not be exceed 1000 IU/day, when it is used in pregnancy with the aim of prophylaxis.

- **Route of administration and method:**

DESIFEROL is administered orally. You can use it with or without food.

If your doctor has told you that you will use 1/2 (half) tablets per day, follow the instructions below on how to break the DESIFEROL tablets.

- Place the tablets on a flat, hard surface with the notch facing upwards (e.g. a table or bench).
- After placing the index fingers of the two hands on the notch tips, push the tablet to break it (Figures 1 and 2).

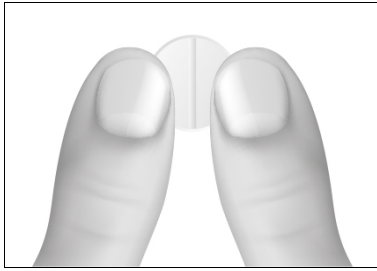


Figure 1

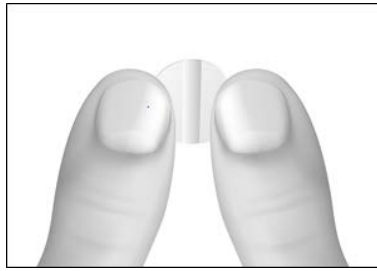


Figure 2

Figures 1 and 2: Dividing the DESIFEROL notched tablet in half by breaking easily.

- **Different age groups:**

**Use in children:**

It is applied as stated in the instructions section for proper use and dose/administration frequency.

DESIFEROL should not be used in children under 12 years of age.

Other forms of DESIFEROL may be more suitable for children. You can consult your doctor or pharmacist about this.

**Use in the elderly:**

It is used as in adults.

- **Special use cases:**

**Kidney failure:**

DESIFEROL should not be used in patients with severe renal impairment.

**Liver failure:**

No dosage adjustment is required in patients with hepatic impairment.

*If you have 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 have accidentally used more than the prescribed dose or if a child has taken this medicine by mistake, please talk to your doctor or seek emergency medical attention to assess the risks and advise.

An excess of vitamin D causes hypercalcemia with increased calcium levels in the blood and urine. Symptoms of hypercalcemia are; nausea, vomiting, early diarrhea and later constipation, thirst, abdominal pain, mental disorders, bone pain, loss of appetite, fatigue, headache, muscle and joint pain, muscle weakness, excessive thirst, excessive urination, kidney stone formation, kidney calcification, kidney failure, calcium deposition in soft tissues, EKG changes, irregular heartbeat and pancreatic inflammation.

*If you have used more than you should use from DESIFEROL, talk to a doctor or pharmacist.*

**If you forget to use DESIFEROL:**

If you forget to use it, take the missed dose as soon as you remember. Then take the next dose at the right time as your doctor has told you. However, if the missed dose is close to the next dose, skip the missed dose and take the next dose as normal.

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

**If you stop using DESIFEROL:**

If you have any further questions on the use of the medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, there may be side effects in people who are sensitive to the substances contained in DESIFEROL.

**If any of the following occur, stop using DESIFEROL and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:**

- Swollen face, lips, tongue or throat
- Difficulty swallowing
- Hives and shortness of breath

These are all very serious side effects. If you have one of these, it means you have a serious allergy to DESIFEROL. You may need emergency medical attention or hospitalization.

Side effects are listed as shown in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients.

Not known: It can be seen in too few patients to be determined with the available data.

Side effects associated with DESIFEROL may include:

**Uncommon**

- Hypercalcemia (too much calcium in the blood)
- Hypercalciuria (too much calcium in the urine)

**Rare**

- Skin rash
- Itching
- Hives (urticaria)

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

### **5. How to store DESİFEROL?**

*Keep this medicine out of the sight and reach of children in its original package.*

Store at room temperature below 25°C and away from light.

#### **Use in accordance with expiry date.**

*Do not use DESİFEROL after the expiry date which is stated on the package.*

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

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

#### ***Marketing Authorization Holder:***

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