

Package leaflet: Information for the patient

Desunin 10 000 IU

Desunin 25 000 IU

soft capsules

cholecalciferol (vitamin D₃)

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, ask your doctor or pharmacist.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Desunin is and what it is used for

Desunin contains the active substance cholecalciferol, better known as Vitamin D₃. Cholecalciferol regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Desunin is indicated for:

- Prevention and treatment of vitamin D deficiency in adults.

- For prevention of vitamin D deficiency

Desunin 25 000 IU is used in adults only in the cases where therapeutic adherence is not obtained with the daily dosing of low dosages of cholecalciferol.

2. What you need to know before you take Desunin

Do not take Desunin

- If you are allergic to cholecalciferol (vitamin D₃) or any of the other ingredients of this medicine (listed in section 6).

- if you have high levels of calcium in the blood (hypercalcaemia) or in the urine (hypercalciuria)

- if you suffer from kidney stones (nephrolithiasis) or calcium deposits in the kidneys (nephrocalcinosis).

- If you have high levels of vitamin D in the body (hypervitaminosis D).

- If you suffer from a kidney disease (renal failure) (see section “Warnings and precautions”).

Warnings and precautions

Talk to your doctor or pharmacist before taking Desunin, especially:

- if you need to follow a treatment with Desunin for a long period and at high doses.

- if you are elderly person and you are already taking medicines to treat heart diseases (cardiac glycosides or diuretics). In this case, you should check calcium levels in the blood and urine.

- if you are already taking medicines containing vitamin D, food added with vitamin D, or milk enriched with vitamin D.

- if you suffer from a chronic inflammatory disease that may involve all organs called sarcoidosis.

- if you have an impairment of kidney function, as vitamin D levels in the body may be altered.

- if you tend to experience kidney stones containing calcium.

- if you have a severe renal insufficiency: in this case other forms of vitamin D should be used.

- if you take this medicinal product for a long term treatment, especially if you are an elderly patient. In this case your doctor will monitor calcium levels in the blood and urine and kidney function. In case of need your doctor will reduce the dose.

- if you have an imbalance of your parathyroid hormone levels (pseudohypoparathyroidism)

Inform your doctor if you have any of the following conditions, as an increase of the dosage as indicated in the section 3.” How to take Desunin” could be needed:

- if you are obese.

- if you suffer from digestive disorders (intestinal malabsorption, mucoviscidosis, or cystic fibrosis).

- if you suffer from a liver disease (hepatic insufficiency).

Children

Desunin soft capsules should not be given to infants or children under 18 years of age.

Other medicines and Desunin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

4. Possible side effects

5. How to store Desunin

6. Contents of the pack and other information

In particular, tell your doctor if you are taking the following medicines, as they can reduce or increase the effect of Desunin:

- Other medicines containing vitamin D.

- Medicines used for the treatment of epilepsy (anticonvulsants or barbiturates), such as phenytoin, phenobarbital, primidone, etc.

- Medicines to reduce fats in the blood such as colestipol, colestyramine, orlistat and laxatives (such as paraffin oil).

- Medicines containing aluminium or magnesium (such as antacids), to treat too much acid in the stomach that can go up to the oesophagus.

- Thiazide diuretics, medicines to treat high blood pressure, increasing the production of urine.

- Digitalis, a medicine to treat some heart disorders.

- Medicines used to treat tuberculosis, as rifampicin or isoniazid.

- Imidazole antifungal agents (such as ketoconazole), medicines used to stop the growth of fungal organisms.

- Actinomycin, a medicine to treat cancer.

- Glucocorticoids, medicines to treat inflammation.

- Warfarin, a medicine used to thin blood.

- Medicines for the heart (cardiac glycosides) because you need to be controlled by a doctor, have an ECG if necessary, and control your calcium levels.

Desunin with food and drink and alcohol

Tell your doctor if you take other medicines containing vitamin D, food added with vitamin D, or in case milk enriched with vitamin D is used, so that he/she can take into account the total dose of vitamin D taken and avoid excessive doses.

The intake of high quantities of alcohol for a long time (chronic alcoholism) decreases vitamin D deposits in the liver.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Desunin should not be used during pregnancy and breast-feeding. However, your doctor may decide that your clinical conditions necessarily require a treatment with vitamin D at lower dosages.

Pregnancy

Your doctor will prescribe you vitamin D during the first 6 months of pregnancy only if strictly necessary, due to the risk of harmful foetal effects (see section 3: “If you take more Desunin than you should”).

However, as vitamin D deficiency is harmful to both the foetus and the mother, when required, your doctor will prescribe you vitamin D during pregnancy at lower dosages.

Breast-feeding

When required, your doctor will prescribe you vitamin D at lower dosages during breast-feeding. This does not replace the administration of vitamin D to the infant.

Driving and using machines

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

3. How to take Desunin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The doses and duration of the treatment shall be assessed by your doctor based on your health conditions.

Do not exceed the doses indicated by your doctor.

Take the dose orally.

Take Desunin with meals.

pliega/folded 37 mm

FRONT

<div><div><div><div></div><div>VIATRIS</div></div></div></div>				<div><div><div>Date: 24 JAN 2025</div><div>Time: 14:22</div></div></div>					
Description		Desunin, 25000 IU, 4		No. of colours		Page Count			
Component Type	Leaflet (Insert)	Site Barcode/DataMatrix	N/A	1		1 of 2			
Affiliate Item Code	3361190	Viatis SAP No.	400575883	Colours		<div>Black</div>			
Superseded Affiliate Item Code	N/A	Vendor Job No.	N/A	Non-Print Colours		<div>Cutting Die</div>			
TrackWise/GLAMS Job No.	3361190	Artwork Proof No.	7	Equate CMYK with					
MA No.	PA23266/005/002	Client Market	Ireland	Main Font		Helvetica Neue LT Pro	Body Text Size 9 pt		
Supplier SAP No.	N/A	Barcode Info	N/A	Dimensions		160x360 mm folded to 160x37 mm	Min Text Size used 9 pt		
New Supplier Code	TBC	3D Render ID	N/A	Keyline/Drawing No.		N/A			
Superseded Supplier Code	N/A	GTIN	N/A						
Packing Site/Printer		Catalent Italy SpA (Aprilia - IT)							
Sign-offs									

