

Package leaflet: Information for the user
Desunin 4000 IU tablets
Colecalciferol (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
2. What you need to know before you take Desunin
3. How to take Desunin
4. Possible side effects
5. How to store Desunin
6. Contents of the pack and other information

1. What Desunin is and what it is used for

Desunin contains vitamin D₃ which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue. Desunin is used to treat vitamin D₃ deficiency in adults and adolescents.

2. What you need to know before you take Desunin

Do not take Desunin

- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have kidney stones.

If any of the above applies to you, talk to your doctor or pharmacist before taking Desunin.

Warnings and precautions

Talk to your doctor or pharmacist before using Desunin

- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- when using other drugs containing vitamin D.
- if you have kidney problems or have had kidney stones.

Other medicines and Desunin

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

- Cholestyramine (used to treat high cholesterol).
- Phenytoin or barbiturates (used to treat epilepsy).
- Laxatives which contain paraffin oil.
- Thiazide diuretics (to treat high blood pressure).
- Glucocorticoids (to treat inflammation).
- Cardiac glycosides (to treat heart conditions), e.g. digoxin.

Desunin with food and drink

Desunin can be taken with food.

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.

During pregnancy the daily intake should not exceed 600 IU vitamin D.

Desunin should only be used during pregnancy if vitamin D deficiency has been clinically established. Desunin can be used during breast-feeding. Vitamin D₃ passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Driving and using machines

Desunin has no known effects on ability to drive or use machines.

Desunin contains sucrose and isomalt

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Desunin.

3. How to take Desunin

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

The recommended dose is 1 tablet every day. The daily dose shall not exceed 4000 IU (one tablets). The tablets can be swallowed whole or crushed. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in children

Desunin is not intended for use in children under 12 years due to lack of study data.

If you take more Desunin than you should

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

If you forget to take Desunin

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

If you stop taking Desunin

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop taking Desunin and seek immediate medicinal help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing

Uncommon (occurs in less than 1 out of 100 patients): Hypercalcaemia (increased levels of serum calcium) and hypercalciuria (increased levels of urine calcium).

Rare (occurs in less than 1 out of 1 000 patients): Pruritus, rash and urticaria.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Desunin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP.

The expiry date refers to the last day of the month.

Do not store above 30°C. Store the tablets in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.



6. Contents of the pack and other information

What Desunin contains

- The active substance is colecalciferol 100 microgram corresponding to 4000 IU Vitamin D₃.
- The other ingredients are pregelatinized maize starch, isomalt (E-953), magnesium stearate, sucrose, sodium ascorbate, medium chain triglycerides, silica colloidal anhydrous, modified food (maize) starch and all-rac-alpha-tocopherol.

What Desunin looks like and contents of the pack

Desunin is a white to light yellow, oblong, tablet, 16 mm long with a score line.

The score is only to facilitate for ease of swallowing and not divide into equal doses.

30, 70 or 90 tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan Products Ltd.,

Station-Close, Potters-Bar,

Hertfordshire, EN6 1TL, UK

Meda Health Sales Ireland Limited, Unit 34/35,

Block A, Dunboyne Business Park, Dunboyne,

Co.Meath, Ireland.

Manufacturer

Rottapharm Ltd.,

Damastown Industrial Park,

Mulhuddart, Dublin 15, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Desunin: Ireland and United Kingdom

Divisun: Denmark, the Netherlands, Norway and

Sweden

This leaflet was last approved in August 2018

Mylan

56UK2068430-00

L1320A

2154