PACKAGE LEAFLET:
INFORMATION FOR THE USER

Desunin 800 IU tablets

colecalciferol

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- In this leaflet Desunin 800 IU tablets will be called Desunin.

In this leaflet:

1. WHAT DESUNIN IS AND WHAT IT IS USED FOR

Desunin contains vitamin D_3 which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Desunin is used to prevent and treat vitamin D_3 deficiency in adults and adolescents.

Your doctor may prescribe Desunin as an adjunct to specific bone loss medication.

Ask your doctor, pharmacist or other health personal if you have further questions and always follow their instructions.

2. BEFORE YOU TAKE DESUNIN

Do not take Desunin

- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of Desunin.
- 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.

Take special care with 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.

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

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- 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.

Taking Desunin with food and drink

Desunin can be taken with food.

Pregnancy, breast-feeding and fertility

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 D_3 passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Ask your doctor or pharmacist for advice before taking Desunin during pregnancy, if you are breast feeding or if you are planning to have a baby.

Driving and using machines

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

Important information about some of the ingredients of Desunin
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 Desunin exactly as your doctor has told you. You should 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 5 tablets.

The tablets can be swallowed whole or crushed.

Use in children
Desunin is not intended for use in children.

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Desunin 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DESUNIN

Keep out of the reach and sight of children.

Do not use Desunin after the expiry date which is stated on the carton or on the bottle after Exp date. The expiry date refers to the last day of the month.

Do not store above 30°C. Store the tablets in the original container, in order to protect from light. Keep the container tightly closed in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Desunin contains
- The active substance is colecalciferol 20 microgram corresponding to 800 IU Vitamin D_3.
- The other ingredients are pregelatinised maize starch, isomalt (E 953), magnesium stearate sucrose, sodium ascorbate, medium chain triglycerides, silica colloidal anhydrous, sodium starch octenyl succinate (E 1450) and all-rac-alpha-tocopherol.

What Desunin looks like and contents of the pack
Desunin is a white to light yellow, biconvex, tablet, 7 mm in diameter.

30, 60 or 90 tablets in blisters.
250 tablets in plastic bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Meda Pharmaceuticals Ltd
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