PACKAGE LEAFLET: INFORMATION FOR THE USER

Colecalciferol 2000 IU film-coated tablets

colecalciferol (Vitamin D_3)

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.

The full name of your medicine is Colecalciferol 2000 IU film-coated tablets. It is referred to as 'colecalciferol tablets' throughout this leaflet.

What is in this leaflet

1. What colecalciferol tablets are and what they are used for
2. What you need to know before you take colecalciferol tablets
3. How to take colecalciferol tablets
4. Possible side effects
5. How to store colecalciferol tablets
6. Contents of the pack and other information

1. WHAT COLECALCIFEROL TABLETS ARE AND WHAT THEY ARE USED FOR

Colecalciferol tablets contain the active substance colecalciferol (vitamin D_3) which regulates which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Colecalciferol tablets are used to treat vitamin D_3 deficiency in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COLECALCIFEROL TABLETS

Do not take colecalciferol tablets:
- 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 kidney stones
- if you have calcium deposits in your kidneys
- if you have hypervitaminosis D (increased levels of vitamin D in the blood)

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

Warnings and precautions
Talk to your doctor or pharmacist before using colecalciferol tablets:
- if you suffer from sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes),
- when using other products containing vitamin D.
- if you have problems with your parathyroid hormone levels (pseudohypoparathyroidism).
- if you have kidney problems or have had kidney stones.

Your doctor may want you to have regular blood and urine tests to check the amount of calcium and phosphate in your blood, or the level of calcium in your urine.

Other medicines and colecalciferol tablets
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.

Colecalciferol tablets with food and drink
Colecalciferol tablets can be taken with food.

Children and adolescents
Colecalciferol tablets are not suitable for children and adolescents up to 18 years.

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.

Pregnancy
You should not take this medicine during pregnancy without a confirmed vitamin D deficiency and your doctor finds it absolutely necessary for you.
Where there is a vitamin D deficiency the recommended dose is dependent on national guidelines, however, the maximum recommended dose during pregnancy is 4,000 IU/day vitamin D_3.
For treatment during pregnancy at higher doses, colecalciferol tablets are not recommended during pregnancy.

Breast-feeding
Colecalciferol tablets can be used during breastfeeding. Vitamin D passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Driving and using machines
Colecalciferol tablets have no known effects on ability to drive or use machines.

Colecalciferol tablets contain sucrose and lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking colecalciferol tablets.

Colecalciferol tablets contain sodium
Colecalciferol tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE COLECALCIFEROL TABLETS

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 or 2 tablets every day (equivalent to 2000-4000 IU/day).
The tablets can be swallowed whole.

Use in children
Colecalciferol tablets are not suitable for children and adolescents up to 18 years.

If you take more colecalciferol tablets 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 colecalciferol tablets
Do not take a double dose to make up for a forgotten dose.

If you stop taking colecalciferol tablets
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 colecalciferol tablets 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 (may affect up to 1 in 100 people):
- Too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomachache, feel very thirsty, have muscle weakness, drowsiness or confusion,

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kidney stones, kidney calcification, calcification in tissues outside the skeleton, cardiac arrhythmias (heart rhythm problems).
- Too much calcium in your urine (hypercalciuria).

Rare (may affect up to 1 in 1,000 people):
- Pruritus, rash and urticaria.

Not known (frequency cannot be estimated from the available data):
- Constipation, flatulence, nausea, abdominal pain, diarrhea.

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 via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COLECALCIFEROL TABLETS

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 25˚C. Keep the blister in the outer carton in order to protect from light.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Colecalciferol tablets contain
- The active substance is colecalciferol (Vitamin D_3)
  - each colecalciferol 2000 IU Film-coated Tablet contains 50 micrograms of colecalciferol corresponding to 2000 IU vitamin D_3.
- The other ingredients:
  - Tablet core: lactose (as lactose monohydrate), powdered cellulose, modified food starch, maize starch, croscarmellose sodium, sucrose, colloidal anhydrous silica, magnesium stearate, sodium ascorbate, medium chain triglycerides, All-rac-alpha-tocopherol.
  - Coating: polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, quinoline yellow aluminum lake (E104), yellow iron oxide (E172).

See also section 2.

What colecalciferol tablets look like and contents of the pack
Colecalciferol 2000 IU Film-coated Tablets are yellow coloured, round, 9 mm diameter biconvex film-coated tablets, embossed 'S' on one side. Pack sizes: 30, 90 and 100 film-coated tablets in opaque PVC/PVdC-Alu blisters and box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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