PACKAGE LEAFLET: INFORMATION FOR THE USER

Colecalciferol 800 IU Film-coated Tablets
Colecalciferol 1000 IU Film-coated Tablets
Colecalciferol 7000 IU Film-coated Tablets
Colecalciferol 30000 IU Film-coated Tablets

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.

What is in this leaflet

1. What Colecalciferol Film-coated Tablets are and what they are used for
2. What you need to know before you take Colecalciferol Film-coated Tablets
3. How to take Colecalciferol Film-coated Tablets
4. Possible side effects
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1. WHAT COLECALCIFEROL FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

The active substance of Colecalciferol Film-coated Tablets is vitamin D_3.

Vitamin D helps the body to absorb calcium and enhances bone formation and decreases the level of parathyroid hormone (PTH).

This medicine is recommended in the following cases:
- For certain bone conditions, such as thinning of the bone (osteoporosis), when it will be given to you with other medicines.
- To prevent or treat vitamin D deficiency. Vitamin D deficiency may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D (e.g. when you are pregnant).

Colecalciferol Film-coated Tablets are used in adults, the elderly and adolescents.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COLECALCIFEROL FILM-COATED TABLETS

Do not take Colecalciferol Film-coated Tablets if:
- if you are allergic to vitamin D or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of calcium in your blood or urine
- if you have kidney stones or calcium deposits in your kidneys
- if you have severe renal impairment
- if you are already taking additional doses of vitamin D (e.g. multivitamins or food supplements containing vitamin D).

Warnings and precautions
If any of the following applies to you, please tell your doctor:
- You have a high tendency to kidney stone formation
- You have cancer or any other condition that may have affected your bones
- You have parathyroid hormone imbalance (pseudo-hypoparathyroidism).

If you have any of the following conditions, your doctor will monitor the levels of calcium or phosphate in your blood, or the level of calcium in your urine:
- If you are on long term treatment with this medicine
- If you have kidney problems
- If you suffer from "sarcoidosis"; an immune system disorder which may affect your liver, lungs, skin or lymph nodes.

Other medicines and Colecalciferol Film-coated Tablets
Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following medicines:
- diuretics (water tablets) – your blood calcium levels will be monitored regularly
- corticosteroids ('steroids' e.g. prednisolone, dexamethasone) – your dose of Vitamin D may need to be increased
- cholestyramine (a cholesterol lowering medicine) or laxatives (e.g. paraffin oil) – they reduce vitamin D absorption
- heart medicines (cardiac glycosides) – you should be monitored by a physician and possibly your ECG and your blood calcium levels will be monitored
- anticonvulsants (for the treatment of epilpsy), sleeping medicines (e.g. hydantoin, barbiturates) or primidone – these reduce the effect of vitamin D
- calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin – these decrease blood calcium levels
- calcium containing products in high doses: these increase the risk of high blood calcium levels
- magnesium containing products (e.g. antacids) – these should not be used during treatment with vitamin D
  because of the risk of high magnesium levels
- phosphorus containing products in large doses – these increase the risk of high phosphate blood levels.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, or breast-feeding, ask your doctor for advice before taking this medicine. If you are breast-feeding, your doctor will monitor the levels of calcium or phosphate in your blood, or the level of calcium in your urine.

Driving and using machines
There is no known effect on your ability to drive or use machines.

Colecalciferol Film-coated Tablets contain lactose and sucrose
If your doctor has previously told you that you have an intolerance to certain sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE COLECALCIFEROL FILM-COATED TABLETS

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

The tablets can be taken with or without food.

Dosage

The amount of Colecalciferol will depend on your vitamin D levels and on the response given to the treatment.

Prevention of vitamin D deficiency (maintenance):
- for adults and elderly: 800-1600 IU/day or equivalent
  weekly or monthly dose.
- for adults and elderly with osteoporosis: maximum 2000 IU/day or equivalent weekly or monthly dose.

Treatment of severe vitamin D deficiency for the adults and elderly (loading dose):
- 800-4000 IU/day or equivalent weekly or monthly dose.

Patients with kidney problems
Your doctor may arrange regular blood and/or urine tests for you.

Use in Children
Colecalciferol Film-coated Tablets are not suitable for children under 12 years.

For adolescents (12-18 years):
- 800 IU daily depending on the severity of the disease and the patient`s response to treatment. Should only be given under medical supervision.

If you take more Colecalciferol Film-coated Tablets than you should
You may develop the following symptoms: loss of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, tiredness, confusion, having to pass more urine than usual, bone pain, kidney problems, and in severe cases, irregular heartbeat, coma or even death.

If you take too many tablets, contact your doctor

immediately or go to the emergency department of the nearest hospital. Take the packet and any remaining tablets with you.

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 Film-coated 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 side effects (may affect up to 1 in 100 people):
- too much calcium in your blood (hypercalcaemia) – symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, a need to pass more water than usual, muscle weakness, drowsiness and confusion
- too much calcium in your urine (hypercalciuria).

Rare side effects (may affect up to 1 in 1,000 people):
- 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 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 FILM-COATED TABLETS

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

Blister: Store below 25°C.
Store in the original package in order to protect from light.
Tablet container: Store in the original tablet container in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Film-coated Tablets contains
The active substance of the product is colecalciferol (vitamin D_3).

Colecalciferol 800 IU Film-coated Tablets: Each film-coated tablet contains 8 mg colecalciferol concentrate (powder form) (equivalent to 20 µg colecalciferol = 800 IU vitamin D_3).
250 film-coated tablets in plastic HDPE container with LDPE cap, in a box.

Colecalciferol 1000 IU Film-coated Tablets: Each film-coated tablet contains 10 mg colecalciferol concentrate (powder form) (equivalent to 25 µg colecalciferol = 1000 IU vitamin D_3).

Colecalciferol 7000 IU Film-coated Tablets: Each film-coated tablet contains 70 mg colecalciferol concentrate (powder form) (equivalent to 175 µg colecalciferol = 7000 IU vitamin D_3).

Colecalciferol 30000 IU Film-coated Tablets: Each film-coated tablet contains 300 mg colecalciferol concentrate (powder form) (equivalent to 750 µg colecalciferol = 30000 IU vitamin D_3).

The other ingredients:
- Tablet core: cellactose 80 (lactose monohydrate and powdered cellulose (E460 (ii)) modified starch, maize starch, croscarmellose sodium (E468), sucrose, colloidal anhydrous silica (E551), colloidal hydrous silica (E551), magnesium stearate (E572), sodium ascorbate (E301), medium chain triglycerides, DL-alpha-tocopherol (E307).
- Coating: Opadry II Yellow 85F 32659 consisting of polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol, talc (E553b), quinoline yellow aluminum lake (E104), yellow iron oxide (E172).

What Colecalciferol Film-coated Tablets look like and contents of the pack

Colecalciferol 800 IU Film-coated Tablets:
Yellow coloured, round, 6.1 mm diameter film-coated tablets with smooth convex surface on both sides.
Pack sizes: 30, 60 or 90 film-coated tablets in opaque PVC/PVdC-Alu blisters and box.
250 film-coated tablets in plastic HDPE container with LDPE cap, in a box.

Colecalciferol 1000 IU Film-coated Tablets:
Yellow coloured, round, 7.2 mm diameter film-coated tablets with smooth convex surface on both sides and 'D' embossed on one side.
Pack sizes: 30, 60 or 90 film-coated tablets in opaque PVC/PVdC-Alu blisters and box.

Colecalciferol 7000 IU Film-coated Tablets:
Yellow coloured, round, 7.2 mm diameter film-coated tablets with smooth convex surface on both sides and 'W' embossed on one side.
Pack sizes: 4, 8, 12 or 32 film-coated tablets in opaque PVC/PVdC-Alu blisters and box.

Colecalciferol 30000 IU Film-coated Tablets:
Yellow coloured, round, 13.2 mm diameter film-coated tablets with smooth convex surface on both sides.
Pack sizes: 1, 2, 3, 4, 6, 8 or 12 film-coated tablets in opaque PVC/PVdC-Alu blisters and box.

Not all pack sizes may be marketed.

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