

PACKAGE LEAFLET

Package leaflet: Information for the user

Colecalciferol EQL Pharma 800 IU tablets Colecalciferol EQL Pharma 2000 IU tablets

colecalfiferol

Read all of this leaflet carefully before you start using 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 Colecalciferol EQL Pharma is and what it is used for
2. What you need to know before you use Colecalciferol EQL Pharma
3. How to use Colecalciferol EQL Pharma
4. Possible side effects
5. How to store Colecalciferol EQL Pharma
6. Contents of the pack and other information

1. What Colecalciferol EQL Pharma is and what it is used for

Colecalciferol EQL Pharma contains the active substance colecalciferol (vitamin D₃). Vitamin D₃ regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Colecalciferol EQL Pharma 800 IU is used to prevent and treat vitamin D₃ deficiency in adults, elderly and adolescents.

Your doctor may prescribe Colecalciferol EQL Pharma 800 IU as an adjunct to specific bone loss medication in adult and elderly patients.

Colecalciferol EQL Pharma 2000 IU is used to treat vitamin D₃ deficiency in adults, elderly and adolescents.

2. What you need to know before you use Colecalciferol EQL Pharma

Do not use Colecalciferol EQL Pharma:

- 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 Colecalciferol EQL Pharma.

Warnings and precautions

Talk to your doctor or pharmacist before using Colecalciferol EQL Pharma:

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

Other medicines and Colecalciferol EQL Pharma

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

Especially tell your doctor if you take any of the following 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.
- Orlistat (to treat obesity).
- Phosphorus containing products (to clean bowel before endoscopy, surgery or X-ray examination) in high doses – these increase the risk of high phosphate blood levels.

Colecalciferol EQL Pharma with food and drink

Colecalciferol EQL Pharma 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.

Colecalciferol EQL Pharma should only be used during pregnancy if you have been diagnosed with vitamin D deficiency by a doctor.

Colecalciferol EQL Pharma 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

Colecalciferol EQL Pharma has no known effects on ability to drive or use machines.

Colecalciferol EQL Pharma contains sodium, sucrose and isomalt

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

3. How to use Colecalciferol EQL Pharma

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The tablets cannot be divided for dosing and so the appropriate formulation should be used to achieve the recommended dose which is as follows:

Use in adults and elderly

Prevention of vitamin D deficiency (maintenance):

- 800 – 1600 IU/day
- for patients with osteoporosis: maximum 2000 IU/day

Treatment of vitamin D deficiency:

- 800 – 4000 IU/day.

After one month of treatment, your doctor may lower the dose to 800 – 1600 IU/day or a weekly or monthly equivalent.

Use in adolescents (12-18 years)

Prevention of vitamin D deficiency:

- 800 IU/day

Treatment of vitamin D deficiency:

- 800 – 1600 IU/day

The daily dose should not exceed 2000 IU per day.

After one month of treatment, your doctor may lower the dose to 800 – 1600 IU/day or a weekly or monthly equivalent.

The tablets can be swallowed whole or crushed.

Use in children

Colecalciferol EQL Pharma is not intended for use in children under 12 years due to lack of data.

If you take more Colecalciferol EQL Pharma 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 EQL Pharma

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

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.

Serious side effects

Stop taking Colecalciferol EQL Pharma 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.

Other side effects

Uncommon (*may affect up to 1 in 100 people*): Hypercalcaemia (increased levels of serum calcium) and hypercalciuria (increased levels of urine calcium).

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

Not known (*frequency cannot be estimated from the available data*): Hypersensitivity reactions

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 HPRA Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colecalciferol EQL Pharma

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 carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°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 protect the environment.

6. Contents of the pack and other information

What Colecalciferol EQL Pharma contains

- The active substance is colecalciferol. Each tablet contains 20 microgram or 50 microgram (corresponding to 800 and 2000 IU Vitamin D₃ respectively)
- The other ingredients are all-rac-alpha-tocopherol (E307), isomalt (E953), magnesium stearate, modified food (maize) starch, pregelatinized maize starch, sodium ascorbate (E301), sucrose and medium chain triglycerides.

What Colecalciferol EQL Pharma looks like and contents of the pack

Colecalciferol EQL Pharma 800 IU is white to off white, biconvex, round, uncoated tablets, plain on both sides, 7 mm in diameter.

Colecalciferol EQL Pharma 2000 IU is white to off white, oblong, uncoated tablets, plain on both sides, 14 mm long.

Colecalciferol EQL Pharma 800 IU: 100 tablets in plastic bottle.

Colecalciferol EQL Pharma 2000 IU: 100 tablets in plastic bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

EQL Pharma AB
Stortorget 1
222 23 Lund
Sweden

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

Ireland, Netherlands, Norway and Sweden: Colecalciferol EQL Pharma

This leaflet was last revised in MM/YYYY

Other sources of information

Detailed information on this medicine is available on the website of HPRA (www.hpra.ie).