

PATIENT INFORMATION LEAFLET (PIL)

MULTIZAN® D3 10 000

CHOLECALCIFEROL

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Multizan® D3 10000 tablets (cholecalciferol) are and what they are used for
2. What you need to know before you take Cholecalciferol
3. How to take Cholecalciferol tablets
4. Possible side effects
5. How to store Cholecalciferol tablets
6. Contents of the pack and other information

1. What Multizan® D3 10000 tablets (Cholecalciferol) are and what they are used for

Multizan® D3 10000 tablets contain the active ingredient Cholecalciferol. Cholecalciferol is a form of vitamin D used in the prevention and treatment of vitamin D deficiency conditions. It may also be prescribed for certain bone conditions, such as thinning of the bone (osteoporosis) when it will be given to you with other medicines.

Cholecalciferol 10 000 IU is the equivalent of 0.25 milligrams vitamin D3, which is involved in bone formation.

The active ingredient Cholecalciferol is identical to the Cholecalciferol that is found in the human body. It is found in the diet and is also produced in the skin after exposure to the sun.

Deficiency of vitamin D may occur when your diet or lifestyle does not provide you with enough vitamin D or when your body requires more vitamin D (for instance when you are pregnant).

If you are planning to get pregnant or you are pregnant and you require extra vitamin D do not take it without medical supervision.

2. What you need to know before you take Cholecalciferol Tablets

Do not take Cholecalciferol tablets

- If you are allergic (hypersensitive) to Cholecalciferol or any of the other ingredients in the tablets (these are listed in section 6. Contents of the pack and other information)
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you are suffering from kidney failure, have kidney stones (renal calculi) or have a tendency to form kidney stones
- if you have high levels of vitamin D in your blood (hypervitaminosis D).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cholecalciferol tablets:

- if you suffer from heart disease or narrowing of the arteries
- if you suffer from sarcoidosis (a multisystem chronic inflammatory condition which can affect your lungs, heart and kidneys), then there is a risk of increased conversion of vitamin D into its active form
- if you are taking medicines containing vitamin D, or eating foods or drinking beverages enriched with vitamin D.

Your doctor may want you to have regular blood tests to check the amount of calcium in your blood.

Children and adolescents

Multizan[®] D3 10000 tablets (cholecalciferol) should only be given to children and adolescents aged 6 and over.

Other medicines and Cholecalciferol tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines which you have bought without a prescription.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines for epilepsy such as barbiturates or other anti-convulsants (e.g. carbamazepine, phenobarbital, phenytoin, primidone)
- other vitamin D containing medicines including multi-vitamins
- medicines to control the rate of your heart beat (e.g. digoxin, digitoxin)
- diuretics (water tablets) such as bendroflumethiazide
- calcium supplements
- medicines to treat tuberculosis e.g. rifampicin, isoniazid
- medicines leading to fat malabsorption e.g. orlistat, cholestyramine, liquid paraffin
- medicines to treat fungal infections i.e. ketoconazole, itraconazole

- actinomycin (a medicine used to treat some forms of cancer) as it may interfere with the metabolism of vitamin D
- glucocorticosteroids (steroid hormones such as hydrocortisone or prednisolone).

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. If you require extra vitamin D do not take it without medical supervision because too much vitamin D may harm your baby.

Driving and using machines

Cholecalciferol should not affect your ability to drive or operate machinery.

3. How to take Multizan® D3 10000 tablets

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

Recommended Doses

Adults

- **Treatment of vitamin D deficiency:** 5 tablets once weekly for 4-8 weeks, followed by maintenance therapy, as directed by your doctor.
- **Prevention of vitamin D deficiency:** 1 tablet every 5-10 days or as directed by your doctor. Higher doses may be required in certain populations.
For pregnant and breastfeeding women 1 tablet every 5-7 days.
- **In osteoporosis (you will also be taking other medicines for this):** 5 tablets once in two weeks during 6 months.

Children and adolescents (6-18 years)

- **Treatment of vitamin D deficiency:** 1 tablet (10 000 IU) every 2-3 days during 4-8 weeks or as directed by the doctor.
- **Prevention of vitamin D deficiency:** 1 tablet every 10-14 days or as directed by the doctor. Higher doses may be required in certain populations.

If you have problems absorbing vitamin D or have other conditions such as excess body weight the dose may be different and will depend on your medical condition.

It is important not to exceed the prescribed dose.

Multizan® D3 10000 tablets with food and drink

The tablets should be swallowed whole with a glass of water, preferably with the main meal of the day.

Use in children and adolescents

Multizan® D3 10000 tablets should only be given to children and adolescents aged 6 and over.

If you take more Multizan® D3 10000 tablets than you should

If you accidentally take several tablets too many tell your doctor or get other medical advice immediately.

If possible, take the tablets, the box and this leaflet with you to show the doctor.

If you forget to take Multizan® D3 10000 tablets

If you forget to take your tablets, take them as soon as possible. Then take the next dose at the correct time, in accordance with the instructions given to you by your doctor. However, if it is almost time to take the next dose, do not take the dose you have missed; just take the next dose as normal.

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, Cholecalciferol can cause side effects, although not everybody gets them.

Side effects with Cholecalciferol may include:

Uncommon side effects

(affecting less than 1 in 100 people)

- too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion
- too much calcium in your urine (hypercalciuria).

Rare side effects

(affecting less than 1 in 1000 people)

- skin rash
- itching

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.

5. How to store Multizan® D3 10000 tablets

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

Store below 30°C.

Store in the original package 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 Multizan® D3 10000 tablets contain

The active substance is Cholecalciferol. Each tablet contains:10 000 IU Cholecalciferol (equivalent to 0.25 milligrams vitamin D3).

The other ingredients are Microcrystalline cellulose PH102, Colloidal hydrated silica, Dicalcium phosphate, Magnesium stearate, Sodium croscarmellose.

What Multizan® D3 10000 tablets look like and contents of the pack

Multizan® D3 10000 are red brown, round, film-coated tablets with “D10K” printed on one side with black ink.

It is available in blister packs containing 15, 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: LAMYRA LLP, Great Britain (address: Scottish Provident House, 1st Floor, 76-80 College Road, Harrow, Middlesex, HA1 1BQ, Great Britain).

Manufacturer: Quest Vitamins Middle East FZE, UAE (address: Plot S20708A, Jebel-Ali Free Zone, Dubai, UAE).

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