

D-CURE[®] 25,000 IU Oral Solution

Cholecalciferol

Consumer Medication Information Leaflet (RiMUP)

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What Cholecalciferol (D-cure) is used for

Cholecalciferol (D-cure) 25,000IU Oral Solution is a vitamin product containing cholecalciferol (equivalent to vitamin D3). Vitamin D can be found in some foods and also produced by the body when skin is exposed to sunlight. Vitamin D helps the kidneys and intestine absorb calcium and it helps build bones [refer to section Before you take Cholecalciferol (D-cure)].

Cholecalciferol (D-cure) 25,000IU Oral Solution is used:

- For prevention of vitamin D deficiency when there is significant risk of deficiency or/and increased demand for vitamin D
- With other medicines to treat certain bone conditions, such as thinning of the bone (osteoporosis)
- To treat vitamin D deficiency that has been confirmed by laboratory tests

How Cholecalciferol (D-cure) works

In its biologically active form Vitamin D, stimulates intestinal calcium absorption, incorporation of calcium into the bone, and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive

and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate. The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of vitamin D3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D.

Before you use Cholecalciferol (D-cure)

When you must not use it

Do not take Cholecalciferol (D-cure) if

- You are allergic to vitamin D or any other ingredients of Cholecalciferol (D-cure) (refer to section Product description: Ingredients)
- You have hypercalcaemia (high levels of calcium in the blood)
- You have hypercalciuria (high levels of calcium in the urine) You have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism)
- You have renal calculi (kidney stones)
- You have hypervitaminosis D (high levels of vitamin D in the blood).
- You take other preparations contain Vitamin D.

Do not take Cholecalciferol (D-cure) if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Cholecalciferol (D-cure).

Before you start to use it

- Before you take Cholecalciferol (D-cure) you should tell your doctor if you:
- Are undergoing treatment with certain medicines used to treat heart disorders (e.g. cardiac glycosides, such as digoxin)
 - Have sarcoidosis (an immune system disorder which may cause increased levels of

vitamin D in the body)

- Are taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D
- Are likely to be exposed to a lot of sunshine whilst using Cholecalciferol (D-cure)
- Taking additional supplements containing calcium. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are using Cholecalciferol (D-cure)
- Have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.
- if experience symptoms similar to those of an overdose, shortly after starting treatment, even though following the recommended dosage. Talk to your doctor immediately, as this may be due to a previously undetected hereditary metabolic disease (idiopathic infantile hypercalcaemia)

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.

This high strength formulation is not recommended for use in pregnant and breastfeeding women.

Driving and using machines

There is limited information on the possible effects of this medicine on your ability to drive. However, it is not expected that it would affect your ability to drive or to operate machinery.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have

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recently taken any other medicines, including medicines obtained without a prescription. It is important that you inform your doctor if you are already being treated with any of the following:

- Medicines that act on the heart or kidneys, such as cardiac glycosides (e.g. digoxin) or diuretics (e.g. bendroflumethazide). When used at the same time as vitamin D these medicines
- may cause a large increase in the level of calcium in the blood and urine
- Medicines containing vitamin D or eating food enrich with vitamin D, such as, some types of vitamin D-enriched milk
- Actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g. clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body process vitamin D
- The following medicines because they can interfere with the effect or the absorption of vitamin D:
 - antiepileptic medicine (anticonvulsants), barbiturates
 - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D
 - medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol)
 - certain medicines for weight loss that reduce the amount of fat your body absorbs (e.g. orlistat)
 - certain laxatives (such as liquid paraffin)

Taking Cholecalciferol (D-cure) with food and drink

You should take this medicine preferably together with a large meal

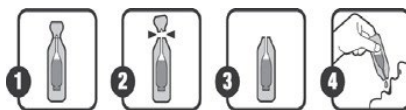
to help your body absorb the vitamin D. You can also mix the solution with cold or lukewarm food, to help you take this medicine. For detailed information, see section "How to use Cholecalciferol (D-cure)".

How to use Cholecalciferol (D-cure)

- How much and when to use it

Always take Cholecalciferol (D-cure) exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should take Cholecalciferol (D-cure) preferably together with a large meal. This medicine has a delicate taste of olive oil. The contents of the ampoule are to be emptied directly into the mouth and swallowed orally as per the diagram below.



To help you take this medicine, the full contents of the single-dose oral solution (in ampoule) may be emptied onto a spoon and taken orally. Cholecalciferol (D-cure) can also be taken by mixing the contents of the ampoule with a small amount of cold or lukewarm food immediately before use. Make sure the entire dose is taken. Cholecalciferol (D-cure) is only for oral use.

Use in children and adolescents

The recommended dose for:

Prevention of vitamin D deficiency in 0-1 years:

1 ampoule of Cholecalciferol (D-cure) 25,000 IU every 8 weeks

Prevention of vitamin D deficiency in 1-18 years:

1 ampoule of Cholecalciferol (D-cure) 25,000 IU every 6 weeks

Treatment of vitamin D deficiency in 0-18 years:

1 ampoule of Cholecalciferol (D-cure) 25,000 IU once every 2 weeks for 6 weeks (followed by

maintenance therapy of 400-1000 IU/day).

In children, Cholecalciferol (D-cure) can be mixed with a small amount of children's foods, yogurt, milk, cheese or other dairy products.

Do not mix this medicine into a bottle of milk or container of soft food, in case your child does not consume the whole portion, and does not receive the full dose. You should make sure that the entire dose is taken.

For children who are no longer breast-feeding you should give the prescribed dose with a substantial meal.

Do not store any product or food mixture that contains Cholecalciferol (D-cure) for use at a later time or a next meal.

Use in pregnancy and breast-feeding

This high strength formulation is not recommended.

Use in adults

The recommended dose for:

Prevention of vitamin D deficiency:

1 ampoule of Cholecalciferol (D-cure) 25,000 IU once monthly. Higher doses may be required based on the advice of your doctor.

Addition to specific therapy for osteoporosis:

1 ampoule of Cholecalciferol (D-cure) 25,000 IU once monthly.

Treatment of vitamin D deficiency:

1 ampoule of Cholecalciferol (D-cure) 25,000 IU once weekly for 6-8 weeks, followed by maintenance therapy (1400-2000 IU once daily may be required), based on the advice of your doctor.

How long to use it

Do not stop taking Cholecalciferol (D-cure) without first discussing it with your doctor. If you have any further questions on the use of this

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medicine, ask your doctor or pharmacist.

If you forget to use it

If you forget to take a dose of Cholecalciferol (D-cure), take the forgotten dose as soon as possible. Then, take the next dose at the correct time. 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 use too much (overdose)

If you or your child takes more medicine than prescribed, stop using this medicine and contact your doctor. If it is not possible to talk to a doctor, go to the nearest hospital emergency department and take the medicine package with you.

The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood (hypercalcaemia and hypercalciuria) shown by lab test.

While you are using Cholecalciferol (D-cure),

- Things you must and must not do

Contact your doctor if any of the following applies to you:

- undergoing treatment with certain medicines used to treat heart disorders (e.g. cardiac glycosides, such as digoxin)
- have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body)
- taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D
- likely to be exposed to a lot of sunshine whilst using Cholecalciferol (D-cure)
- take additional supplements

containing calcium
- have kidney damage or disease

- Things to be careful of

While you are on this medicine, your doctor may want to monitor the levels of calcium in blood or urine to make sure they are not too high whilst you are using Cholecalciferol (D-cure).

Side effects

Like all medicines, Cholecalciferol (D-cure) can cause side effects, although not everybody gets them. If the side effects don't go away after a few days, or you feel unwell in any other way, talk to your doctor before you take your next dose. The following adverse events can be observed:

Psychiatric disorders

Confusional state, aggression, insomnia

Gastrointestinal disorders

Nausea, abdominal pain, diarrhoea, vomiting, gastrointestinal disorder, dyspepsia

Nervous system disorders

Dizziness, flushing

Metabolism and nutrition disorders

Hypercalcaemia, hypercalciuria, decreased appetite, tetany

Skin and subcutaneous tissue disorders

Pruritus, urticaria, rash, hyperhidrosis

The side effects are the result of overdose.

Depending on the dose and duration of treatment, acute (cardiac arrhythmias, nausea, vomiting, psychic symptoms, disturbances of consciousness) and chronic (increased urgency to urinate, increased thirst, loss of appetite, weight loss, kidney stones, kidney calcification, calcification in tissues outside the

skeleton) consequences can occur. A fatal outcome has been reported in very rare cases.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Cholecalciferol (D-cure)

Keep out of the reach and sight of children.

Do not use Cholecalciferol (D-cure) after the expiry date which is stated on the carton and labels after "Exp".

The expiry date refers to the last day of the month shown. Store below 30°C in the original carton in order to protect the contents from light.

Do not freeze or refrigerate. Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of packagings and medicines no longer required. This way you will help to protect the environment.

Product description

- What it looks like

Cholecalciferol (D-cure) is a clear, slightly yellow, oily liquid with an orange odour. It is supplied in transparent PVC/PVDC/PE ampoules.

It is available in pack of 4 or 12 PVC/PVDC/PE ampoules. Not all pack sizes may be marketed.

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Ingredients

- The active substances is cholecalciferol (Vitamin D3)

- The other ingredients are tocopherol acetate, polyglyceryl oleate(E475), olive oil, refined, sweet orange peel oil.

Product Registration Number
MAL18086102ARZ

Manufacturer

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Belgium

For:

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Product registration holder

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