Due to the different legal status in different countries certain information to the prescription status has been added to the PL. The added information is marked in grey shadings. If it is not indicated for prescription the grey shaded parts will be deleted in the national version.

Package leaflet: Information for the patient

Cholecalciferol mibe 500 IE, tabletten

Cholecalciferol (vitamin D_3)

For use in infants, children, adolescents and adults

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.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What <trade name> 500 IU is and what it is used for

<trade name> 500 IU contains vitamin D_3 (equivalent to cholecalciferol) for the regulation of the absorption and metabolism of calcium and for the integration of calcium into bone tissue.

<trade name> 500 IU is used
- for prophylaxis of rickets (impaired bone hardening during the growth phase) and osteomalacia (softening of bones) in children, adolescents and adults.
- for prophylaxis of vitamin D deficiency in children, adolescents and adults with an identified risk.
- for the supportive treatment of osteoporosis (thinning of bone tissue) in adults.

2. What you need to know before you take <trade name> 500 IU

Do not take <trade name> 500 IU
- if you are allergic to cholecalciferol or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from hypercalcemia (high calcium levels in the blood)
- if you have hypercalciuria (high calcium levels in the urine)
- if you have been diagnosed with hypervitaminosis D (high vitamin D levels in the blood)
- if you have nephrocalcinosis (calcification of the kidney)
- if you have kidney stones or your kidney function is severely impaired.

Warnings and precautions
Talk to your doctor or pharmacist before taking <trade name> 500 IU.

Take special care with <trade name> 500 IU,
- if you suffer from pseudohypoparathyreoidism (disorder of the parathyroid hormone balance).
- if you have a tendency to get calcium-containing kidney stones.
- if you have problems in calcium and phosphate excretion through your kidneys.
- if you are being treated with medicines to increase urine output (benzothiadiazine derivatives) or if your mobility is greatly restricted, as there is a risk of hypercalcemia (high calcium levels in the blood) and hypercalciuria (high calcium levels in the urine) in this case.
- if you have sarcoidosis (a specific disease that affects the connective tissue of the lungs, skin and joints), as there is a risk of increased conversion of vitamin D into its active form. In such cases, blood and urine calcium levels should be monitored by the doctor.
- if your liver function is impaired.
- if you or your child experience symptoms similar to those of an overdose (see section 3) shortly after starting treatment, even though you are following the recommended dosage. In this case, talk to your doctor immediately, as this may be due to a previously undetected hereditary metabolic disease (idiopathic infantile hypercalcemia).

In patients with mild to moderate renal insufficiency treated with <trade name> 500 IU, the effect on the calcium and phosphate balance should be monitored.

Tell your doctor if you or your child take other medicinal products, dietary supplements (e.g. multivitamins) or certain food types (e.g. fortified infant formula) containing vitamin D, as the vitamin D dose of <trade name> 500 IU must be taken into account. Combination of <trade name> 500 IU with metabolites or analogues of vitamin D (e.g. calcitriol) have to be avoided. Additional vitamin D or calcium should only be administered under medical supervision. In such cases, serum and urinary calcium levels must be monitored.
Combination with calcium supplements should take into account all sources of calcium and not exceed e.g. 1 000 mg/day.

During long-term treatment with <trade name> 500 IU, the calcium levels in serum and urine should be monitored regularly and renal function checked via measurements of serum creatinine. If necessary, a dose adjustment should be made on the basis of serum calcium levels.

During treatment with <trade name> 500 IU at daily doses above 1 000 IU of vitamin D, your doctor should monitor the calcium levels in your blood and urine and check your kidney function as well. Such monitoring is particularly important in elderly patients and when treating at the same time with cardiac glycosides (medicines to stimulate heart muscle function) or diuretics (medicines that stimulate urine output). In the event of increased calcium levels in the blood (hypercalcemia) or urine (hypercalciuria) or other signs of impaired kidney function, treatment has to be discontinued.

Infants and toddlers
<trade name> 500 IU should be used with particular caution in infants and toddlers, as they may not be able to swallow the tablets. It is advisable to dissolve the tablets as stated in section 3 “How to take <trade name> 500 IU” or to use drops.

Other medicines and <trade name> 500 IU

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

The effect of <trade name> 500 IU can be diminished by the simultaneous use of
- phenytoin (medicine used to treat epilepsy) or barbiturates (medicines used to treat epilepsy and sleep disorders and for anaesthesia)
- glucocorticoids ('steroids' e.g. prednisolone, dexamethasone), medicines used to treat certain allergic conditions
- rifampicin and isoniazid (medicines used to treat tuberculosis)
- cholestyramine or colestipol (cholesterol lowering ion exchange resins) or laxatives (e.g. paraffin oil) – they reduce vitamin D absorption
- orlistat (medicine used to treat obesity/adiposity)
- actinomycin (medicine used to treat cancer)
- imidazole (antifungal agent).

The effect/side effects of <trade name> 500 IU can be increased by the simultaneous use of
- medicines for increasing urine output/flow (e.g. thiazide diuretics, hydrochlorothiazide):
  A reduction in the elimination of calcium via the kidneys can cause calcium concentrations in the blood to rise (hypercalcemia). Calcium levels in the blood and urine should therefore be monitored during long-term treatment.

When taken at the same time, <trade name> 500 IU can increase the risk of side effects of
- cardiac glycosides (e.g. digoxin, medicines used to increase the functioning of the heart muscles):
  The risk of heart rhythm disturbances can increase as a result of a rise in calcium levels in the blood during treatment with vitamin D. In such cases, the doctor in charge should carry out ECG monitoring as well as monitoring of calcium levels in the blood and urine and of levels of the medicine in the blood.
- products containing magnesium (like antacids):
  The risk of high blood level of magnesium (hypermagnesemia) exists.
- aluminium containing medicines (used for heartburn):
  The long-term use of these medicines should be avoided, because aluminium blood levels may increase.
- phosphate containing products in large doses:
  These products increase the risk of high phosphate blood levels.
- calcitonin, gallium nitrate, bisphosphonates or plicamycin:
  These products decrease the blood calcium levels.

Please note that this information may also apply to recently used medicines.

<trade name> 500 IU with food and drink
<trade name> 500 IU should be taken together with food and drink.

Pregnancy, breast-feeding and fertility
During pregnancy and breast-feeding, adequate vitamin D intake is necessary. 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.

<trade name> 500 IU can be used during pregnancy and breast-feeding.

Pregnancy
Daily doses above 600 IU vitamin D (15 micrograms cholecalciferol, corresponding to more than one tablet of <trade name> 500 IU) should only be taken if clearly indicated by your doctor. During pregnancy, you should not use doses above 4 000 IU vitamin D daily (100 micrograms cholecalciferol, corresponding to 8 tablets daily of <trade name> 500 IU).

Overdose of vitamin D may harm your baby (risk of physical and mental retardation, as well as heart and eye diseases).

Breast-feeding
Vitamin D and its metabolites pass into breast milk, which needs also to be taken into account if your child is receiving additional vitamin D.

Fertility
Normal endogenous levels of vitamin D are not expected to have any adverse effects on fertility. The impact of high doses of vitamin D on fertility is unknown.

Driving and using machines
<trade name> 500 IU has no or negligible influence on the ability to drive and use machines.

<trade name> 500 IU contains lactose and sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

<trade name> 500 IU contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take <trade name> 500 IU

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

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

The recommended dose is:

For the prophylaxis of rickets and osteomalacia in children, adolescents and adults
1 tablet <trade name> 500 IU daily (equivalent to 0.0125 mg or 500 IU of vitamin D_3).

For the prophylaxis of rickets in preterm newborn infants
Preterm newborn babies
- with a birth weight > 1500 g: 1 tablet <trade name> 500 IU daily (equivalent to 0.0125 mg or 500 IU of vitamin D_3)
- with a birth weight < 1500 g (700 - 1500 g): 2 tablets <trade name> 500 IU daily (equivalent to 0.025 mg or 1000 IU of vitamin D_3).

The doctor in charge shall decide on the dose.

For prophylaxis of vitamin D deficiency in children, adolescents and adults with an identified risk

Infants (0 - 12 months):
1 tablet <trade name> 500 IU daily (equivalent to 0.0125 mg or 500 IU of vitamin D_3).

Children, adolescents and adults:
1 - 2 tablets <trade name> 500 IU daily (equivalent to 0.0125 - 0.025 mg or 500 - 1000 IU of vitamin D_3).

For the supportive treatment of osteoporosis in adults
2 tablets <trade name> 500 IU daily (equivalent to 0.025 mg or 1000 IU of vitamin D_3).

Alternatively, national posology recommendations in prevention and treatment of vitamin D deficiency can be followed.

Method of administration

Children, adolescents and adults
Please take the tablets with a sufficient amount of fluid.
Please ask your doctor about the length of treatment required.

Infants and toddlers
Dissolve the tablet on a teaspoon with water or milk and administer the dissolved tablet directly into the child's mouth, preferably during a meal. The disintegration takes 1 - 2 minutes. For accelerating the process of disintegration, spoon should be moved slightly.

Adding tablets to a baby's bottle feed or soft mashed food is not recommended, as complete vitamin D administration cannot be guaranteed.

Nevertheless, if the tablets are to be administered with food, it should first be cooked and then allowed to cool before the tablets are added. When using vitamin-enriched food, the amount of vitamin D that it contains should be taken into account.

Infants are given <trade name> 500 IU from two weeks up until one year of age. In their second year of life, further doses of <trade name> 500 IU are to be recommended, especially during the winter months.

If you take more <trade name> 500 IU than you should
If you or your child take more <trade name> 500 IU than you should, contact a doctor immediately.

The signs of an overdose are not very characteristic, manifesting as nausea, vomiting, initial diarrhoea progressing to constipation, loss of appetite, lassitude, headache, painful muscles and joints, muscle weakness, persistent drowsiness, impaired consciousness, arrhythmia (irregular heartbeat), azotaemia (high nitrogen levels in the blood), increased thirst, increased urinary urge and - at the final stage - dehydration.

Please ask your doctor about the signs of a vitamin D overdose.
There is no specific antidote.

Your doctor will then initiate the necessary countermeasures.

If you forget to take <trade name> 500 IU
Do not take a double dose to make up for a forgotten dose.

If you stop taking <trade name> 500 IU
Your symptoms may return or get worse again if you stop your treatment before you should.

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.

You should stop taking <trade name> 500 IU and immediately contact a doctor if any of the following signs of a **severe allergic reaction** appear:
- swollen face, swollen lips, tongue or throat
- swallowing difficulties
- hives and laboured breathing.

The following side effects can occur:

Uncommon (may affect up to 1 in 100 patients):
Hypercalcemia (high calcium levels in the blood) and hypercalciuria (high calcium levels in the urine)

Rare (may affect up to 1 in 1 000 patients):
Itching, skin rash or nettle rash

Not known (cannot be estimated from the available data):
Gastrointestinal complaints (constipation, flatulence, nausea, abdominal pain, diarrhoea)

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 <[to be completed nationally]>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <trade name> 500 IU

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 the carton after "Exp.:". The expiry date refers to the last day of that month.

Storage conditions
Do not store above 25 ºC.
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 <trade name> 500 IU contains
- The active substance is: cholecalciferol.
  Each tablet contains 12.5 micrograms of cholecalciferol (equivalent to 500 IU vitamin D_3), as cholecalciferol concentrate, powder form.
- The other ingredients are:
  lactose monohydrate, microcrystalline cellulose, maize starch, modified maize starch, sodium starch glycolate (type A) (Ph.Eur.), sucrose, silica colloidal anhydrous, magnesium stearate (Ph.Eur.), sodium ascorbate, medium-chain triglycerides, all-rac-alpha-tocopherol.

What <trade name> 500 IU look like and contents of the pack
The tablets are white to yellowish, round and slightly biconvex with a size of about 5 mm.
<trade name> 500 IU is available in blister packs containing 20, 50, 100 and 200 tablets.
Not all pack sizes may be marketed.

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In het register ingeschreven onder:
RVG 113281

This medicinal product is authorised in the member states of the EEA under the following names:

Duitsland:	Dekristol® 500 I.E.
Nederland:	Cholecalciferol mibe 500 IE, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in november 2024.

Other sources of information:
<Latest approved information [add type of information e.g. product information, educational material, video etc] on this medicine is available by scanning [the QR code][other two-dimensional (2D) bar code][Near-field Communication (NFC)] included in the <PL> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website >>