Package leaflet: Information for the patient

Cholecalciferol mibe 1000 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.
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 Cholecalciferol mibe 1000 IE, tabletten is and what it is used for

Cholecalciferol mibe 1000 IE, tabletten 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.

Cholecalciferol mibe 1000 IE, tabletten 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 Cholecalciferol mibe 1000 IE, tabletten

Do not take Cholecalciferol mibe 1000 IE, tabletten
- if you are allergic to cholecalciferol or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from hypercalcaemia (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 kidney stones.

Warnings and precautions
Talk to your doctor or pharmacist before taking Cholecalciferol mibe 1000 IE, tabletten.

Take special care with Cholecalciferol mibe 1000 IE, tabletten
- 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).
- if your mobility is greatly restricted, as there is a risk in this case of hypercalcaemia (high calcium levels in the blood) and hypercalciuria (high calcium levels in the urine).
- 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 you have parathyroid hormone imbalance (pseudohypoparathyroidism), as vitamin D requirements may be reduced by the sometimes normal sensitivity to vitamin D. In this case, there is a risk of long-term overdose. For such patients, more manageable active substances with vitamin D activity are available.

If your kidneys are not working properly and you are being treated with Cholecalciferol mibe 1000 IE, tabletten, the effect of treatment on the calcium and phosphate balance should be monitored by your doctor.

If other medicines containing vitamin D are prescribed, the vitamin D dose consumed when using Cholecalciferol mibe 1000 IE, tabletten must be taken into account. Additional vitamin D or calcium should only be administered under medical supervision. In such cases, calcium levels in the blood and urine must be monitored.

Infants and toddlers
Cholecalciferol mibe 1000 IE, tabletten 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 Cholecalciferol mibe 1000 IE, tabletten” or to use drops.

Daily doses above 500 IU
During long-term treatment with Cholecalciferol mibe 1000 IE, tabletten in daily doses above 500 IU, calcium levels in the blood and urine should be monitored regularly and kidney function checked via measurements of serum creatinine. Such monitoring is particularly important in elderly patients and during concomitant treatment with cardiac glycosides (medicines to promote the function of the heart muscle) or diuretics (medicines to promote urination). In the event of hypercalcaemia (increased calcium level in the blood) or signs of reduced renal function, the dose must be reduced or the treatment discontinued. If hypercalciuria occurs (more than 7.5 mmol equivalent to 300 mg calcium/24 hours), the dose is to be reduced or treatment discontinued.

Other medicines and Cholecalciferol mibe 1000 IE, tabletten
Tell your doctor or pharmacist if you are taking/ using, have recently taken/ used or might take/ use any other medicines.

The effect of Cholecalciferol mibe 1000 IE, tabletten can be affected 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 (medicines used to treat certain allergic conditions)
- rifampicin and isoniazid (medicines used to treat tuberculosis)
- ion exchangers such as cholestyramine (medicine used to lower high cholesterol levels), laxatives containing liquid paraffin
- actinomycin (medicine used to treat cancer)
- imidazole (antifungal agent)
- orlistat (medicine used to treat adiposity).

The effect/side effects of Cholecalciferol mibe 1000 IE, tabletten can be increased by the simultaneous use of
- vitamin D metabolites or analogues (e.g. calcitriol):
  Combination with Cholecalciferol mibe 1000 IE, tabletten is recommended only in exceptional cases under strict medical supervision.
- medicines for increasing urine output (thiazide diuretics):

A reduction in the elimination of calcium via the kidneys can cause calcium concentrations in the blood to rise (hypercalcaemia). Calcium levels in the blood and urine should therefore be monitored during long-term treatment.

When taken at the same time, Cholecalciferol mibe 1000 IE, tabletten can increase the risk of side effects of

- cardiac glycosides (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.

Cholecalciferol mibe 1000 IE, tabletten with food and drink
Cholecalciferol mibe 1000 IE, tabletten should be taken together with food and drink.

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.

Pregnancy
Daily intake up to 500 IU/d
In this dose range, there are no known risks to date.
Long-term overdoses of vitamin D must be avoided during pregnancy, as a resulting hypercalcaemia (increased blood level of calcium) may lead to physical and mental disability as well as to congenital heart and eye diseases in the child.

Daily intake more than 500 IU/d
During pregnancy, Cholecalciferol mibe 1000 IE, tabletten should be taken only when strictly indicated and dosed only as it is absolutely necessary to correct the vitamin D deficiency.
Overdoses of vitamin D must be avoided during pregnancy, as prolonged hypercalcaemia (increased blood level of calcium) may lead to physical and mental disability as well as to congenital heart and eye diseases in the child.

Breast-feeding
Women may breast-feed during treatment with Cholecalciferol mibe 1000 IE, tabletten. As vitamin D and its metabolites are excreted in breast milk, this should be borne in mind however when administering additional vitamin D to the child.

Driving and using machines
Cholecalciferol mibe 1000 IE, tabletten is not known to have any effect on driving or using machines.

Cholecalciferol mibe 1000 IE, tabletten 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.

Cholecalciferol mibe 1000 IE, tabletten 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 Cholecalciferol mibe 1000 IE, tabletten

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
½ tablet Cholecalciferol mibe 1000 IE, tabletten 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: 1/2 tablet Cholecalciferol mibe 1000 IE, tabletten daily (equivalent to 0.0125 mg or 500 IU of vitamin D3)
- with a birth weight < 1500 g (700 - 1500 g): 1 tablet Cholecalciferol mibe 1000 IE, tabletten daily (equivalent to 0.025 mg or 1000 IU of vitamin D3).

The doctor in charge shall decide on the dose.

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

Infants (0 - 12 months):
1/2 tablet Cholecalciferol mibe 1000 IE, tabletten daily (equivalent to 0.0125 mg or 500 IU of vitamin D_3).

Children, adolescents and adults:
½ - 1 tablet Cholecalciferol mibe 1000 IE, tabletten daily (equivalent to 0.0125 – 0.025 mg or 500 – 1000 IU of vitamin D_3).

For the supportive treatment of osteoporosis in adults
1 tablet Cholecalciferol mibe 1000 IE, tabletten daily (equivalent to 0.025 mg or 1000 IU of vitamin D_3).

The tablet can be divided into equal halves.
Please take the tablets with a sufficient amount of fluid.
Please ask your doctor about the length of treatment required.

Daily doses above 500 IU/d
During long-term treatment with Cholecalciferol mibe 1000 IE, tabletten in daily doses above 500 IU, calcium levels in the blood and urine should be monitored regularly and kidney function checked via measurements of serum creatinine. If necessary, a dose adjustment should be made on the basis of blood calcium levels.

Use in 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 Cholecalciferol mibe 1000 IE, tabletten from two weeks up until one year of age. In their second year of life, further doses of Cholecalciferol mibe 1000 IE, tabletten are to be recommended, especially during the winter months.

If you take more Cholecalciferol mibe 1000 IE, tabletten than you should
If you or your infant take more Cholecalciferol mibe 1000 IE, tabletten 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, 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 Cholecalciferol mibe 1000 IE, tabletten
Do not take a double dose to make up for a forgotten dose.

If you stop taking Cholecalciferol mibe 1000 IE, tabletten
Your symptoms may get worse again or return if you stop your treatment or end it before you should. Please ask your doctor for more information.

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.

The frequencies of side effects are not known, as no major clinical studies allowing any estimation of frequencies have been conducted.

You should stop taking Cholecalciferol mibe 1000 IE, tabletten and immediately contact your 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:
- Hypercalcaemia (high calcium levels in the blood) and hypercalciuria (high calcium levels in the urine)
- Gastrointestinal complaints such as constipation, flatulence, nausea, abdominal pain or diarrhoea
- Hypersensitivity reactions such as itching, skin rash or nettle rash.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl

5. How to store Cholecalciferol mibe 1000 IE, tabletten

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

Do not use this medicine after the expiry date which is stated on blister and the the carton after “Exp.:”. The expiry date refers to the last day of that month.

<u>Storage conditions</u>

Do not store above 25ºC.
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 Cholecalciferol mibe 1000 IE, tabletten contains
- The active substance is: cholecalciferol.
  Each tablet contains 25 microgram of cholecalciferol (equivalent to 1000 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 Cholecalciferol mibe 1000 IE, tabletten look like and contents of the pack
The tablets are white to yellowish, oval and elongated with a score line.
Cholecalciferol mibe 1000 IE, tabletten is available in blister packs containing 20, 30, 50, 100 and 200 tablets.
Not all pack sizes may be marketed.

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In het register ingeschreven onder:
RVG 113282

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

Austria:	Dekristolmin 1000 I.E. Tabletten
Germany:	Dekristol® 1000 I.E
Netherlands:	Cholecalciferol mibe 1000 IE, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in januari 2020.