CalciD-Denk

Effervescent tablet - oral use
Mineral and vitamin combination preparation
Active substances: calcium + cholecalciferol (vitamin D_3)
For use in adults

Package leaflet: Information for the patient

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 CalciD-Denk is and what it is used for

CalciD-Denk are effervescent tablets containing calcium and vitamin D_3 - two important substances in bone formation.

CalciD-Denk is taken

- for the prevention and treatment of calcium and vitamin D deficiency states in the elderly
- as an adjunct to specific osteoporosis therapy for patients at risk of vitamin D and calcium deficiency.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take CalciD-Denk

Do not take CalciD-Denk:

- if you are allergic to calcium, cholecalciferol (vitamin D_3) or any of the other ingredients of this medicine (listed in section 6)
- if you have an abnormally high level of calcium in your blood or urine
- if you have severely impaired kidney function
- if you have kidney stones
- if you have abnormally high levels of vitamin D in your blood.

Warnings and precautions

Talk to your doctor or pharmacist before taking CalciD-Denk

- if you are on long-term treatment

Version: 50001095-005

- if you have impaired kidney function or a strong predisposition to kidney stone formation
- if you have sarcoidosis (an immune system disorder that can lead to an increased vitamin D level in the body)
- if you are immobilised with osteoporosis
- if you are taking other vitamin D or calcium preparations. Additional doses of calcium and vitamin D must be taken only under strict medical supervision.

Your doctor will decide whether a calcium and/or vitamin D_3 preparation may be used in these circumstances.

If you use CalciD-Denk for osteoporosis, it is advisable to have the blood calcium (calcaemia) level determined prior to the start of treatment.

In the event of long-term treatment with CalciD-Denk, the blood calcium level must be monitored regularly. Depending on the result, your doctor may decide to lower the dose or discontinue the treatment.

If your kidney function is impaired and you are treated with CalciD-Denk, your doctor should monitor the effect of the treatment on the calcium and phosphate level.

Children and adolescents
CalciD-Denk effervescent tablets are not intended for use in children and adolescents.

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

Calcium carbonate can prevent the absorption of tetracycline products (a type of antibiotic) taken at the same time. For this reason, tetracycline products should be administered at least two hours before or four to six hours after CalciD-Denk effervescent tablets.

Medicines that contain bisphosphonates (for the treatment of osteoporosis) or sodium fluoride (to strengthen tooth enamel) should be taken at least three hours before CalciD-Denk effervescent tablets.

Calcium can interfere with the effect of levothyroxine. For this reason, levothyroxine should be taken at least four hours before or four hours after CalciD-Denk effervescent tablets.

The effect of quinolone antibiotics may be impaired by simultaneous calcium administration. For this reason, take quinolone antibiotics two hours before or six hours after CalciD-Denk.

Rifampicin, phenytoin or barbiturates can decrease the effect of vitamin D_3 because they increase its rate of metabolism.

Calcium salts can interfere with the absorption of iron, zinc or strontium. Consequently, iron, zinc or strontium products should be taken two hours before or after a calcium product.

Other medicines that can lead to interactions with CalciD-Denk effervescent tablets are: thiazide diuretics (water pills, which are used to treat high blood pressure or oedema), cardiac glycosides (e.g. digitalis, for the treatment of heart conditions), corticosteroids (for the treatment of inflammation or as immunosuppressants), ion exchange resins such as cholestyramine (for the treatment of high blood cholesterol levels), laxatives such as paraffin oil or orlistat (for the treatment of obesity).

Other products containing calcium or vitamin D: Additional doses of calcium and vitamin D can lead to a significant increase in blood calcium levels and cause harmful side effects. Such products must not be taken together with CalciD-Denk effervescent tablets except under close medical supervision.

CalciD-Denk with food and drink
CalciD-Denk effervescent tablets can be taken with or between meals.

Oxalic acid (e.g. in spinach, sorrel and rhubarb) and phytic acid (in wholemeal products) can inhibit calcium uptake. For this reason, you should not take CalciD-Denk within two hours before or after eating food with a high oxalic or phytic acid content.

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
CalciD-Denk should not be used during pregnancy and breast-feeding due to the high vitamin D dosage. There have been isolated reports of healthy children being born despite high doses of vitamin D being used to treat thyroid underactivity (hypoparathyroidism) in the mothers.

Breast-feeding
Due to the high vitamin D content, CalciD-Denk should not be taken while breast-feeding. Calcium and vitamin D_3 pass into human milk.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. However, an adverse effect is unlikely.

CalciD-Denk 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. May be harmful to the teeth.

CalciD-Denk contains sodium
This medicine contains 96.1 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 4.8% of the recommended maximum daily dietary intake of sodium for an adult.

CalciD-Denk contains soya oil
CalciD-Denk contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take CalciD-Denk

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 one effervescent tablet per day.

Please dissolve the effervescent tablet in a glass of drinking water (200 ml) and drink the whole contents of the glass.

If you take more CalciD-Denk than you should
If you take more CalciD-Denk than you should, contact your doctor or pharmacist promptly.

The symptoms of hypercalcaemia (an increased level of calcium in the blood) include loss of appetite, nausea, vomiting, constipation, abdominal pain, muscle weakness, drowsiness and confusion, extreme thirst, excessive or unusually heavy urine production and/or frequent urination and bone pain.

If you forget to take CalciD-Denk

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

If you have any further questions on taking 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.

Uncommon: may affect up to 1 in 100 people
If high doses are taken, this can lead to an increased level of calcium in the blood (hypercalcaemia) or in the urine (hypercalciuria).

The symptoms of hypercalcaemia include lack of appetite, nausea, vomiting, constipation, abdominal pain, muscle weakness, drowsiness and confusion, extreme thirst, excessive or unusually strong urine production and/or frequent urination and bone pain.

Rare: may affect up to 1 in 1,000 people
Constipation, digestive disorders, flatulence, nausea, abdominal pain and diarrhoea.

Very rare: may affect up to 1 in 10,000 people
Itching, skin rash, hives and allergic reactions (due to soya oil).

Milk-alkali syndrome (also called Burnett's syndrome; usually occurs only following excessive calcium ingestion); the symptoms are hypercalcaemia, metabolic alkalosis, impaired kidney function and calcium deposits in the soft tissues.

Not known: frequency cannot be estimated from the available data
Hypersensitivity reactions.

Tell your doctor immediately if you experience any of the following signs of a serious allergic reaction: swollen face, swelling of the lips, tongue (angioedema) or throat (laryngeal oedema).

In very rare cases, hydrogenated soya oil may cause allergic reactions.

Patients with impaired kidney function
If you have impaired kidney function, you may be at risk of increased blood phosphate levels, kidney stone formation and increased amounts of calcium in the kidneys.

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

5. How to store CalciD-Denk

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 and tube after “Exp.”. The expiry date refers to the last day of that month.

Shelf life: 3 years.

After opening: 1 month.

Store below 25 °C.

Keep the tube tightly closed.

Tell your pharmacist if you notice any change in the appearance of the effervescent tablets.

Do not use any pack that is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater. 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

Pharmacodynamic properties

Pharmacotherapeutic group: minerals, calcium, combinations with vitamin D and/or other substances, ATC code: A12AX

Vitamin D increases the intestinal absorption of calcium.

Administration of calcium and vitamin D_3 counteracts the increase of parathyroid hormone (PTH) that is caused by calcium deficiency and causes increased bone resorption.

A clinical study of institutionalised patients with vitamin D deficiency indicated that a daily intake of 1,000 mg calcium and 800 IU vitamin D for a period of six months normalised the value of the 25-hydroxylated metabolites of vitamin D_3 and reduced secondary hyperparathyroidism and alkaline phosphatases.

An 18-month, double-blind, placebo-controlled study in 3,270 institutionalised women aged 84+/-6 years who received supplementation with vitamin D (800 IU/day) and calcium phosphate (equivalent to 1,200 mg/day of elemental calcium) showed a significant decrease of PTH secretion. After 18 months, an "intent-to treat" analysis showed 80 hip fractures in the calcium-vitamin D group and 110 hip fractures in the placebo group ($p=0.004$). A follow-up study after 36 months showed 137 women with at least one hip fracture in the calcium-vitamin D group ($n=1,176$) and 178 in the placebo group ($n=1,127$) ($p<0.02$).

Pharmacokinetic properties

Calcium

Absorption: The amount of calcium absorbed via the gastrointestinal tract is approximately 30% of the ingested dose.

Distribution and biotransformation: 99% of the calcium in the body is concentrated in the hard structures of the bones and teeth. The remaining 1% is located in the intra- and extracellular fluids.

Elimination: Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.

Vitamin D

Absorption: Vitamin D is readily absorbed in the small intestine.

Distribution and biotransformation: Cholecalciferol is converted to the active form 25-hydroxycholecalciferol in the liver by hydroxylation. It is then further converted in the kidneys to 1,25-dihydroxycholecalciferol. 1,25-dihydroxycholecalciferol is the metabolite responsible for the increase in calcium absorption.

Elimination: Vitamin D is excreted in faeces and urine.

What CalciD-Denk contains

- The active substances are calcium and cholecalciferol (vitamin D_3).
  Each effervescent tablet contains 1,000 mg calcium (as calcium carbonate) and 22 µg cholecalciferol (vitamin D_3, equivalent to 880 IU).

- The other ingredients are alpha-tocopherol, hydrogenated soya oil, gelatin, sucrose, maize starch, citric acid, sodium hydrogen carbonate, lactose monohydrate, povidone, saccharin sodium, sodium cyclamate, macrogol 6000, simeticone, methyl cellulose, orange juice flavour.

General classification for supply
Medicinal product subject to medical prescription

What CalciD-Denk looks like and contents of the pack
CalciD-Denk effervescent tablets are round, white to off-white biplane effervescent tablets with bevelled edges on both sides.

CalciD-Denk is available in polypropylene tubes with polyethylene tamper-proof-closures.

Pack size: 20 effervescent tablets

Marketing Authorisation Holder
DENK PHARMA GmbH & Co. KG
Prinzregentenstr. 79
81675 München
Germany

Manufacturer of bulk, packaging and batch release
Losan Pharma GmbH
Otto-Hahn-Straße 13
79395 Neuenburg
Germany

This leaflet was last revised in 07/2022.