**Package leaflet: Information for the patient**

**Kollopan 500 mg/400 IU film-coated tablet**
**Kollopan 500 mg/800 IU film-coated tablet**

calcium / cholecalciferol (vitamin $D_3$)

**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.

**What is in this leaflet**


## 1. What <Invented name> is and what it is used for

<Invented name> is used to prevent and treat calcium and vitamin $D_3$ deficiency in elderly, and as an adjunct in the management of osteoporosis, when a risk of deficiency of calcium or vitamin $D_3$ is suspected.
<Invented name> contains calcium and vitamin $D_3$ which both are important components for the formation of bone. Vitamin $D_3$ regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

## 2. What you need to know before you take <Invented name>

**Do not take <Invented name>**
- if you are allergic to calcium, cholecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you have an increased level of calcium in the blood (hypercalcaemia) or urine (hypercalciuria) or you have a condition that can cause an increased level of calcium in your blood or urine.
- if you have an increased level of vitamin D in the blood (hypervitaminosis D).
- if you have kidney stones (nephrolithiasis) or calcium deposits in your kidneys (nephrocalcinosis).
- if you are suffering from severe renal (kidney) impairment or renal failure.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking <Invented name>:
- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).

- when concomitant use of other medicines containing vitamin D or calcium.
- if you suffer from renal insufficiency.
- if you suddenly are confined to bed or sitting for a longer time.

**Children and adolescents**
<Invented name> is not intended for use in children.

**Other medicines and <Invented name>**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment can be affected if this medicine is taken simultaneously with certain other medicines against:
- high blood pressure (thiazide diuretics)
- heart problems (cardiac glycosides such as digoxin)
- high cholesterol (cholestyramine)
- constipation (laxatives, such as liquid paraffin)
- epilepsy (phenytoin or barbiturates)
- inflammatory conditions/suppression of immunity (corticosteroids)

Please make sure your doctor knows if you are taking any of the medicines listed above. Your dosage may need to be adjusted.

If you simultaneously use certain medicines for:
- infection (tetracycline or quinolone antibiotics), you should take these two hours before or six hours after oral intake of <Invented name>.
- thyroid deficiency (levothyroxine), intake should be separated by at least four hours.
- osteoporosis (bisphosphonates), you should take these medicines at least three hours before <Invented name>.
- caries (sodium fluoride), you should take these medicines at least three hours before <Invented name>.

Calcium salts may decrease the uptake of iron, zinc and strontium ranelate. Therefore iron, zinc or strontium ranelate preparations should be taken at least two hours before or after <Invented name>.

Orlistat (used to treat obesity) may disturb the absorption of fat-soluble vitamins, e.g. vitamin $D_3$.

**<Invented name> with food and drink**
The effect can be influenced by food containing oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals). You should wait at least two hours before you take <Invented name> if you have eaten food with high content of oxalic acid or phytic acid.

**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.

During pregnancy <Invented name> should only be used in case of a shown calcium and vitamin

$D_3$ deficiency and the maximum daily dose should not exceed 2500 mg calcium and 4,000 IU vitamin $D_3$.

Calcium and vitamin $D_3$ pass over in breast milk. This should be considered when giving additional vitamin D to the child. A decision must be made whether to discontinue breast-feeding or to discontinue [Invented name] or adjust therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

**Driving and using machines**
<Invented name> has no known effects on ability to drive or use machines.

**<Invented name> contains sucrose and isomalt**
<Invented name> contains sucrose and isomalt. lf you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**<Invented name> 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 <Invented name>

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

The recommended dose is:
- <Invented name> 500 mg/400 IU: 2 tablets daily
or
- <Invented name> 500 mg/800 IU: 1 tablet daily

The tablets can be swallowed whole, divided or crushed.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

**If you take more <Invented name> than you should**
If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

Symptoms of an overdose of <Invented name> are loss of appetite, thirst, abnormal increased urine secretion, nausea, vomiting and constipation.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

*You should stop taking <Invented name> and see your doctor immediately if you experience symptoms of hypersensitivity reactions such as angioedema and laryngeal oedema:*
- swollen face, tongue, lips or throat
- difficulties to swallow
- hives and difficulties to breath
Frequency not known (cannot be estimated from the available data).

*Other side effects that may occur:*

*Uncommon (may affect up to 1 in 100 people):* hypercalcaemia (increased levels of serum calcium) and/or hypercalciuria (increased levels of urine calcium).

*Rare (may affect up to 1 in 1,000 people*): constipation, flatulence, nausea, abdominal pain, diarrhoea, itching, rash and urticaria.

*Very rare (may affect up to 1 in 10,000 people)*: Milk-alkali syndrome (also called Burnett's syndrome) with the following symptoms: frequent urge to urinate, headache, loss of appetite, nausea (feeling sick) or vomiting (being sick), unusual tiredness or weakness, along with elevated levels of calcium in the blood which may results in loss of kidney function. Milk-alkali syndrome is usually only seen when excessive amounts of calcium have been consumed.

**Patients with renal impairment**
Patients with renal impairment are at potential risk of high levels of phosphate in blood, kidney stones formation and calcification of 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. You can also report side effects directly via the national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store <Invented name>

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 label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 <Invented name> contains

The active substances are calcium and cholecalciferol (vitamin $D_3$).
<Invented name> 500 mg/ 400 IU contains
- calcium carbonate corresponding to calcium 500 mg
- cholecalciferol 10 micrograms corresponding to 400 IU vitamin $D_3$

<Invented name> 500 mg/ 800 IU contains
- calcium carbonate corresponding to calcium 500 mg
- cholecalciferol 20 micrograms corresponding to 800 IU vitamin $D_3$

The other ingredients are croscarmellose sodium, povidone, citric acid monohydrate, sodium ascorbate, isomalt (E953), magnesium stearate, sucrose, medium chain triglycerides, colloidal

anhydrous silica, all-rac-alpha-tocopherol, modified food starch, hypromellose, macrogol, paraffin light liquid. See also section 2 ‘<Invented name> contains sucrose and isomalt’ and ‘<Invented name> contains sodium’.

**What <Invented name> looks like and contents of the pack**

<Invented name> 500 mg/ 400 IU is a white to off-white, capsule shaped, biconvex, film-coated tablet with break line, engraved CC 11 on one side, 18 x 8 mm.
<Invented name> 500 mg/ 800 IU is a white to off-white, capsule shaped, biconvex, film-coated tablet with break line, engraved CC 12 on one side, 18 x 8 mm.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

<Invented name> 500 mg/ 400 IU and <Invented name> 500 mg/ 800 IU: 100, 105, 180, 200, 210 tablets in plastic bottles with plastic cap.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

[To be completed nationally]

**This leaflet was last revised in 2026-01-14.**