

Package leaflet: Information for the patient

CALVIDIN 600 mg/400 I.U. chewable tablets

Calcium carbonate and Cholecalciferol

For adults only.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 CALVIDIN 600 mg/400 I.U. chewable tablets is and what it is used for
2. What you need to know before you take CALVIDIN 600 mg/400 I.U. chewable tablets
3. How to take CALVIDIN 600 mg/400 I.U. chewable tablets
4. Possible side effects
5. How to store CALVIDIN 600 mg/400 I.U. chewable tablets
6. Contents of the pack and other information

1. What CALVIDIN 600 mg/400 I.U. chewable tablets is and what it is used for

This medicine contains two active substances calcium and vitamin D3. Calcium is an important constituent of bone and vitamin D3 helps the absorption of calcium by the intestine and its deposition in the bones.

It is used:

- in the correction of vitamin D and calcium deficiencies in the elderly
- in combination with osteoporosis treatment where vitamin D and calcium levels are too low or where there is a high risk of them being too low.

2. What you need to know before you take CALVIDIN 600 mg/400 I.U. chewable tablets

Do not take CALVIDIN 600 mg/400 I.U. chewable tablets

- If you are allergic to calcium, vitamin D or any of the other ingredients of this medicine (listed in section 6)
- If you have an abnormally high level of calcium in the blood (hypercalcaemia) and/or excessive loss of calcium in urine (hypercalciuria)
- If you have a condition that could lead to hypercalcaemia and/or hypercalciuria (e.g. overactive parathyroid glands, a disease of the bone marrow (myeloma), a malignant bone tumour (bone metastases))

- If you are suffering from severe kidney impairment or kidney failure
- If you are suffering from kidney stones (calcium lithiasis) or have calcium deposits in your kidneys (nephrocalcinosis)
- If you are suffering from an excessive supply of vitamin D (hypervitaminosis D)

Warnings and precautions

Take special care with CALVIDIN 600 mg/400 I.U. chewable tablets

- In the case of long-term treatment with CALVIDIN 600 mg/400 I.U. chewable tablets the quantity of calcium in the blood and serum creatinine to assess renal function must be regularly monitored.

This monitoring is particularly important in the elderly and where treatment is being taken at the same time as cardiac glycosides (e. g. Digoxin) and diuretics.

Depending upon the result, your doctor may decide to reduce or even stop your treatment. But therapy should be reduced or preliminary interrupted if urinary calcium level exceeds 7.5 mmol/24 hours (300 mg/24 hours).

- Take into account the intake of vitamin D, calcium and alkali like carbonate from all other sources (e.g. dietary supplements or food) before taking CALVIDIN chewable tablets. As these products already contain vitamin D and calcium carbonate, the additional administration of CALVIDIN may lead to a disease called Burnett Syndrome. Burnett Syndrome (milk alkali syndrome) is a disorder of calcium metabolism with an increase of calcium in the blood. It can be caused by excessive intake of milk, and/or calcium carbonate from other sources or overuse of antacids. This may lead to side effects as listed in section 4. An additional administration of CALVIDIN must therefore be carried out under strict medical supervision with regular monitoring of the calcium content in blood (calcaemia) and urine (calciuria).

Talk to your doctor or pharmacist before taking CALVIDIN 600 mg/400 I.U. chewable tablets:

- If you have had **kidney stones**.
- If you are suffering from an **immune disorder (sarcoidosis)**, as the amount of calcium in your blood and urine must be checked.
- If you are **immobile** and are suffering from **reduced bone mass (osteoporosis)**. This may increase the level of calcium in your blood too much which can cause side effects.
- If you are taking other **medicines containing vitamin D3 or calcium**. This may increase the level of calcium in your blood too much which can cause side effects.
- If you have **impaired renal function**

Children and adolescents

Do not give this medicine to children and adolescents as there is no relevant indication of use in this age group.

Other medicines and CALVIDIN 600 mg/400 I.U. chewable tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular,

- Thiazide diuretics (medicines used to treat high blood pressure), as they may increase the amount of calcium in your blood.
- Oral steroids, as they may reduce the amount of calcium in your blood.
- Orlistat (a medicine used to treat obesity), cholestyramine, laxatives such as paraffin oil, as they may reduce the amount of vitamin D3 you absorb.
- Rifampicin (antibiotic), Phenytoin (a medicine for epilepsy) and barbiturates (medicines which help you sleep), as they may make the vitamin D3 less effective.
- Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects if you take too much calcium.
- Tetracycline antibiotics, as the amount absorbed may be reduced. They should be taken at least 2 hours before, or 4-6 hours after CALVIDIN 600 mg/400 I.U. chewable tablets.
- Estramustin (a medicine used in the chemotherapy), thyroid hormones or medicines containing iron, zinc or strontium, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after CALVIDIN 600 mg/400 I.U. chewable tablets.
- Bisphosphonates (a treatment for bone conditions), fluoride or fluoroquinolones (a type of antibiotic), as the amount absorbed may be reduced. They should be taken at least 3 hours before or after CALVIDIN 600 mg/400 I.U. chewable tablets.

CALVIDIN 600 mg/400 I.U. chewable tablets with food and drink

In the two hours before taking CALVIDIN 600 mg/400 I. U. chewable tablets, you should avoid eating foods containing oxalic acid (e.g. spinach and rhubarb) or phytic acid (e.g. wholegrain cereals), which can reduce calcium absorption.

Pregnancy, breast-feeding and fertility

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 medicine can be used during pregnancy; however, the total daily intake of calcium should not be higher than 1500 mg and the daily intake of vitamin D not higher than 600 I. U.

Therefore, in the case of pregnancy, the daily dose of CALVIDIN 600 mg/400 I. U. chewable tablets must not exceed one tablet per day. Higher amounts may have a negative effect on the unborn child.

During breast-feeding you can use CALVIDIN 600 mg/400 I. U. chewable tablets. As calcium and vitamin D3 pass into breast-milk you have to check with your doctor first if your infant receives any other products containing vitamin D3.

There are no adverse effects on fertility expected when taking CALVIDIN 600 mg/400 I.U. chewable tablets.

In pregnant and lactating women, CALVIDIN 600 mg/400 I.U. chewable tablets should be taken at a distance of two hours from a meal due to a possible decrease of iron absorption.

Driving and using machines

No effects on the ability to drive and use machines are expected.

Excipients

CALVIDIN 600 mg/400 I.U. chewable tablets contains 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 teeth.

The following information can be used if you suffer from diabetes: the content of digestible carbohydrates in CALVIDIN 600 mg/400 I.U. chewable tablets is 0.47 g per chewable tablet.

At a daily dose of 2 chewable tablets this corresponds to 0.08 bread units.

Sodium content

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

3. How to take CALVIDIN 600 mg/400 I.U. chewable tablets

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

Dosage

The usual dose is 1 tablet twice a day for adults and elderly (e.g. one in the morning and one in the evening). Pregnant women should only take 1 tablet per day.

Long term treatment requires monitoring of blood and urine calcium levels, especially important if you have a tendency to develop kidney stones.

Method of Administration

The tablets can be chewed and then swallowed with the aid of some liquid. In exceptional cases (e. g. disabled patients) the tablets can, after consulting a doctor, be sucked.

Duration of treatment

Your doctor will decide the duration of the treatment with CALVIDIN 600 mg/400 I.U. chewable tablets.

If you take more CALVIDIN 600 mg/400 I.U. chewable tablets than you should

If you have taken more CALVIDIN 600 mg/400 I.U. chewable tablets than you should and experience any of the symptoms of overdose, stop taking CALVIDIN 600 mg/400 I.U. chewable tablets and immediately contact your doctor. Symptoms of overdose may include: dehydration, anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones.

In the case of prolonged overdosage, calcium deposits may appear in blood vessels or body tissues.

In the case of major overdosage, cardiac arrest may occur.

If you forget to take CALVIDIN 600 mg/400 I.U. chewable tablets

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

If you stop taking CALVIDIN 600 mg/400 I.U. chewable tablets

If you wish to interrupt or prematurely discontinue the treatment, please consult your physician.

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.

Some rare and very rare side effects might be serious.

Uncommon side effects (occurring in less than 1 in 100 but more than 1 in 1,000 patients)
Increase in blood calcium concentrations (hypercalcaemia) and/or in the excretion of calcium in urine (hypercalciuria).

Rare side effects (occurring in less than 1 in 1,000 but more than 1 in 10,000 patients)
Nausea, abdominal pain, flatulence, bloating, abdominal distension, constipation or diarrhoea; pruritus, rash, urticaria, itching, redness and burning of the skin.

Not known (cannot be estimated from the available data)

Serious allergic (hypersensitivity) reactions such as swelling of the face, lips, tongue or throat;
vomiting.

If any of the side effects gets serious, stop taking this medication and contact your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CALVIDIN 600 mg/400 I.U. chewable tablets

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 the seal strip. The expiry date refers to the last day of that month.

Do not store CALVIDIN 600 mg/400 I.U. chewable tablets above 25°C.

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 CALVIDIN 600 mg/400 I.U. chewable tablets contains

The active substances are: calcium carbonate 1500 mg equivalent to elemental calcium 600 mg cholecalciferol concentrate (powder form) 4 mg equivalent to vitamin D3 10 µg (400 I.U.)

The other ingredients are: xylitol, d-mannitol, magnesium stearate, silica colloidal anhydrous, pregelatinised maize starch, butylated hydroxytoluene (E321), medium-chain triglycerides, sucrose, gelatine, modified maize starch, sodium aluminium silicate, flavouring agents (Tutti frutti 77919- 31 Givaudan). See also section 2 'CALVIDIN D 600 mg/400 I.U. chewable tablets contains sucrose' and 'sodium content'.

What CALVIDIN 600 mg/400 I.U. chewable tablets looks like and contents of the pack

CALVIDIN 600 mg/400 I.U. chewable tablets is a medicinal product in the form of chewable tablets, the tablets are white, biplane in shape with a snap groove and the letters C/D printed on the tablet.

CALVIDIN 600 mg/400 I.U. chewable tablets are available in the form of PVC/PVDC/Aluminium blisters each containing 10 chewable tablets.

The box sizes available contain 20, 30, 50, 60, 100, 300 chewable tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

Manufacturer

Madaus GmbH
51101 Köln

This medicinal product is authorised in the Member States of the EEA under the following names

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| Italy: | Metocal Vitamina D3 600 mg/400 I. U. |
| Ireland: | Calvidin 600 mg/400 I.U. chewable tablets |
| France: | Metocalcium 600 mg/400 I. U. |
| Greece: | Calvidin 600 mg/400 I. U. |
| Portugal: | Calcior-D |
| Germany: | CALCIGEN D 600 mg/400 I. U. chewable tablets |

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