**Package leaflet: Information for the patient**

**Calcomben 500 mg/400 IU chewable tablet**
**Calcomben 500 mg/800 IU chewable tablet**
**Calcomben 1000 mg/800 IU chewable tablet**

calcium / cholecalciferol

**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 Calcomben is and what it is used for

Calcomben is used to prevent and treat calcium and vitamin D deficiency in adults and elderly, and as a supplement in the treatment of osteoporosis, when a risk of deficiency of calcium or vitamin D is suspected. Calcomben contains calcium and vitamin D, both of which are important components for the formation of bone. Vitamin D 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 Calcomben

**Do not take Calcomben**
- 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).
- if you have an increased level of vitamin D in the blood (hypervitaminosis D).
- if you have kidney stones (nephrolithiasis).
- if you are suffering from severely impaired kidney function/kidney failure.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Calcomben:
- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- if you are taking other drugs containing vitamin D or calcium.
- have poor kidney function or high tendency of kidney stone formation.
- if you are suddenly confined to bed or sitting for a longer time.

**Children and adolescents**
Calcomben is not intended for use in children.

**Other medicines and Calcomben**
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 drug is taken simultaneously with certain other drugs for:
- 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 drugs for:
- infection (tetracycline or quinolone antibiotics), you should take these two hours before or six hours after oral intake of Calcomben.
- thyroid deficiency (levothyroxine), intake should be separated by at least four hours.
- osteoporosis (bisphosphonates), you should take these drugs at least three hours before Calcomben.
- caries (sodium fluoride), you should take these drugs at least three hours before Calcomben.

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 Calcomben.

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

**Calcomben with food and drink**
Calcomben can be taken with or without food and drink.

**Pregnancy, 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.

Calcomben can be used during pregnancy, in case of a calcium and vitamin D deficiency. During pregnancy the daily intake should not exceed 2500 mg calcium and 4000 IU vitamin D.

Calcium and vitamin D3 pass over in breast milk and an overdose has to be avoided in the infant. A decision must be made whether to discontinue breast-feeding or to discontinue Calcomben 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**
Calcomben has no known effects on ability to drive or use machines.

**Calcomben contains sucrose**
One tablet contains 0.7 mg (500 mg/400 IU) sucrose or 1.4 mg (500 mg/800 IU and 1000 mg/800 IU) 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.

**Calcomben 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 Calcomben

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:
- Calcomben 500 mg/400 IU: 2 tablets daily
or
- Calcomben 500 mg/800 IU: 1 tablet daily
or
- Calcomben 1000 mg/800 IU: 1 tablet daily

The tablets should be chewed, never swallowed whole.

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

## 4. Possible side effects

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

You should stop taking Calcomben 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).

*Uncommon (may affect up to 1 in 100 people):* excessive amounts of calcium in the blood (hypercalcaemia) or in the urine (hypercalciuria).

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

*Very rare (may affect up to 1 in 10,000 people)*: Itching, rash and hives. 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 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 Calcomben

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.

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 Calcomben contains

The active substances in one tablet are:
-Calcium carbonate corresponding to 500 mg calcium
- Cholecalciferol 10 micrograms corresponding to 400 IU vitamin D3
Or
-Calcium carbonate corresponding to 500 mg calcium
- Cholecalciferol 20 micrograms corresponding to 800 IU vitamin D3
Or
- Calcium carbonate corresponding to 1000 mg calcium
- Cholecalciferol 20 micrograms corresponding to 800 IU vitamin D3

The other ingredients are xylitol (E967), sucrose, medium chain triglycerides, silicon dioxide, DL-alpha tocopherol, modified food starch, sucralose (E955), povidone, citric acid, sodium ascorbate, croscarmellose sodium, flavoring (lemon) and magnesium stearate. See also section 2 Calcomben contains sucrose', Calcomben contains sodium'.

### What Calcomben looks like and contents of the pack

Calcomben 500 mg/ 400 IU is a white to off white, round, chewable tablets, engraved with E4 on one side.

Calcomben 500 mg/ 800 IU is a white to off white, round, chewable tablets, engraved with E5 on one side.

Calcomben 1000 mg/ 800 IU is a white to off white, round, chewable tablets.

Pack sizes:
Calcomben 500 mg/ 400 IU: 60, 90, 100, 120, 180 and 200 tablets in plastic containers made of polyethylene.

Calcomben 500 mg/ 800 IU and Calcomben 1000 mg/ 800 IU: 30, 60, 90 and 100 tablets in plastic containers made of polyethylene.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

EQL Pharma AB
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