

## **Package leaflet: Information for the user**

### **Bencium 500 mg / 800 IU chewable tablets** calcium / colecalciferol (vitamin D3)

**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 Bencium is and what it is used for
2. What you need to know before you take Bencium
3. How to take Bencium
4. Possible side effects
5. How to store Bencium
6. Contents of the pack and other information

#### **1. What Bencium is and what it is used for**

Bencium is a calcium-vitamin D3-supplement.

It is used

- to prevent and treat deficiency of calcium and vitamin D in the elderly.
- for vitamin D and calcium supplementation as, supportive treatment of osteoporosis (brittle bones) for patients who are at risk of vitamin D and calcium deficiency.

#### **2. What you need to know before you take Bencium**

##### **Do not take Bencium**

- if you are allergic to calcium, vitamin D or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of calcium in your blood (hypercalcaemia)
- if you have high levels of calcium in your urine (hypercalciuria)
- if you suffer from overactive parathyroid glands (hyperparathyroidism)
- if you suffer from bone marrow cancer (myeloma)
- if you suffer from cancer that has affected your bones (bone metastases)
- if you have restriction in movement of the limbs (prolonged immobilisation) accompanied with hypercalcaemia and / or hypercalciuria
- if you have kidney stones (nephrolithiasis)
- if you have calcium deposits in your kidneys (nephrocalcinosis)
- if you suffer from an excessive supply of vitamin D (hypervitaminosis D)
- if you have severe kidney problems.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Bencium

- if you are on long-term treatment, especially if you also take diuretics (used in the treatment of high blood pressure or oedema) or cardiac glycosides (used to treat heart disorders).
- if you have impaired renal function.

- if you have sarcoidosis (an immune system disorder that may increase vitamin D levels in the body).
- if you have osteoporosis and at the same time are unable to move around.
- if you take other products containing vitamin D. Additional doses of calcium and vitamin D should be taken under close medical supervision.

### **Children and adolescents**

Bencium chewable tablets are not intended for use in children and adolescents.

### **Other medicines and Bencium**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Other medicines that may influence or be influenced by Bencium are:
  - o thiazide diuretics (used in treatment of high blood pressure or oedema)
  - o cardiac glycosides (used to treat heart disorders)
- If you also take tetracyclines (a type of antibiotics), you should take these at least two hours before or four to six hours after intake of Bencium. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.
- Medicines containing bisphosphonates (used to treat osteoporosis) should be taken at least three hours before intake of Bencium.
- Orlistat (used to treat obesity), cholestyramine (a product to lower raised cholesterol levels) or laxatives such as liquid paraffin may disturb the absorption, and thereby reduce the effect, of fat-soluble vitamins, e.g. vitamin D3.
- Phenytoin (a product for the treatment of epilepsy) or barbiturates (hypnotics) can result in a reduction in the effect of vitamin D.
- Glucocorticoids (e. g. cortisone) can result in a reduction in the effect of vitamin D and a decreased calcium level in the blood.
- Calcium can reduce the effect of levothyroxine (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least four hours before or four hours after Bencium.
- The effect of quinolone antibiotics may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking Bencium.
- Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken at least two hours before or after Bencium.
- HIV integrase inhibitor drugs (antiretroviral drug used to treat HIV, e.g., raltegravir, dolutegravir, elvitegravir): Bencium can reduce the effect of HIV integrase inhibitor drugs if taken at the same time. Consult the patient information leaflet of the HIV integrase inhibitor drug before taking Bencium for recommendation on how to take the medicines.

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

### **Bencium with food and drink**

You can take Bencium at any time, with or without food.

### **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.

Bencium is not recommended during pregnancy in patients without a vitamin D and calcium deficiency.

Where there is a vitamin D deficiency the recommended dose is dependent on national guidelines, however, the maximum daily dose should not exceed 2500 mg calcium and 4,000 IU vitamin D per day.

Long-term overdose of calcium and vitamin D during pregnancy must be avoided since this may lead to high levels of calcium in the blood and may have a negative effect on the unborn child.

Bencium can be used during breast-feeding. As calcium and vitamin D pass into breast-milk check with your doctor first if your child receives any other products containing vitamin D. This should be considered when giving additional vitamin D to the child.

### **Driving and using machines**

Bencium has no influence on your ability to drive and use machines.

### **Bencium contains**

- Benzyl alcohol: This medicine contains 0.0115 mg benzyl alcohol in each chewable tablet. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
- Sorbitol: This medicine contains 52 mg of sorbitol in each 500 mg/800 IU chewable tablet.
- Sodium: This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially ‘sodium-free’.
- Aspartame (E951): This medicine contains 0.5 mg Aspartame in each chewable tablet. Aspartame is a source of phenylalanine which may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- Isomalt (E953) and sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take Bencium**

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

Recommended dose is 1 chewable tablet daily (corresponding to 500 mg of calcium and 800 IU (International Units) of vitamin D3). The dosage is individually decided for you by your doctor.

The tablet has to be chewed before it is swallowed. It can be taken at any time, with or without food.

You should give attention to a sufficient daily intake of calcium by nutrition (i.e. milk products, vegetables, mineral water).

#### **Use in children and adolescents**

Bencium **is not intended** for use in children and adolescents.

#### **If you take more Bencium than you should**

Overdose of Bencium may lead to symptoms such as feeling sick (nausea), vomiting, thirst or excessive thirst, increased urine output, depletion of body fluids or constipation. If an overdose is suspected, contact your doctor or pharmacist immediately.

#### **If you forget to take Bencium**

If you forget to take Bencium, take it as soon as you remember. However, do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking Bencium**

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

*Uncommon:* may affect up to 1 in 100 people

- high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria).

*Rare:* may affect up to 1 in 1,000 people

- feeling sick (nausea), diarrhoea, abdominal pain, constipation, wind, bloating (abdominal distension).
- rash, itching, hives.

**Stop taking Bencium and contact a doctor immediately** if you experience the following allergic reaction (not known as frequency cannot be estimated from the available data):

- swelling of the face, lips, tongue or throat with sudden difficulty breathing and severe 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 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 Bencium**

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 on the tablet container after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Keep the tablet container tightly closed in order to protect from moisture.

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Bencium contains**

- The active substances are calcium carbonate and colecalciferol (vitamin D3). Each chewable tablet contains calcium carbonate equivalent to 500 mg calcium and colecalciferol concentrate (powder form) equivalent to 800 IU (20 micrograms) colecalciferol (vitamin D3).
- The other ingredients are isomalt (E953), xylitol, sorbitol (E420), citric acid, anhydrous, sodium dihydrogen citrate, magnesium stearate, carmellose sodium, flavour Orange "CPB" (containing flavouring substances, mannitol (E421), maltodextrin, glucono lactone (E575), sorbitol (E420), benzyl alcohol, propylene glycol, sodium), flavour Orange "CVT" (containing flavouring substances, mannitol (E421), maltodextrin, glucono lactone (E575), sorbitol (E420), medium-chain triglyceride), silica, colloidal hydrated, aspartame (E951), acesulfam potassium, sodium ascorbate, all-rac-alpha-tocopherol, modified (maize) starch, sucrose, triglycerides medium chain and silica, colloidal anhydrous.

### **What Bencium look like and contents of the pack**

Bencium are white, round orange flavoured chewable tablets with a diameter of 18 mm.

The chewable tablets are available in polypropylene tablet containers with polyethylene stoppers containing a desiccant in the following package sizes:

25, 30, 90 (3 x 30) and 100 (4 x 25) chewable tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder:**

Consilient Health Limited,  
Floor 3, Block 3, Miesian Plaza,  
Dublin 2, D02 Y754,  
Ireland

### **Manufacturer:**

Hermes PHARMA GmbH  
Hans-Urmiller-Ring 52  
82515 Wolfratshausen  
Germany

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

Sweden: Bencium

Finland: Bencium 500 mg / 800 IU chewable tablets

Norway: Bencium 500 mg / 800 IU chewable tablets

**This leaflet was last revised in 2023-12-14**