

Summary Public Assessment Report

Bencium calcium carbonate colecalciferol concentrate (powder)

SE/H/1777/01-02/DC

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Bencium

(Calcium carbonate, colecalciferol)

Chewable tablet

500mg / 800 IU and 500mg / 2000 IU

Calcium / colecalciferol (vitamin D3)

This is a summary of the public assessment report (PAR) for Bencium. It explains how Bencium was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Bencium.

For practical information about using Bencium, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bencium and what is it used for?

Bencium is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Bencium is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Bencium is a calcium-vitamin D₃-supplement and it's used to treat lack of calcium and vitamin D deficiency.

How does Bencium work?

Bencium is a fixed combination of calcium and vitamin D₃. Vitamin D₃ is involved in calcium-phosphorus metabolism. It allows the active absorption of calcium and phosphorus from the intestine and their uptake by bone. Supplementation with calcium and vitamin D₃ corrects latent vitamin D deficiency and secondary hyperparathyroidism.

How is Bencium used?

The pharmaceutical form of Bencium is chewable tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Bencium have been shown in studies?

As Calcium carbonate, colecalciferol are well-known substances, and its use in the treatment of;
500mg / 800 IU

- *for the prevention and treatment of vitamin D and calcium deficiency in the elderly*
- *as vitamin D and calcium supplement as an adjunct to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency,*

500mg / 2000 IU

- *for treatment of calcium and vitamin D deficiency,*

are well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of calcium carbonate, cholecalciferol in above mentioned indications.

What are the possible side effects of Bencium?

For the full list of all side effects reported with Bencium, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

Why is Bencium approved?

The use of Bencium in the treatment of

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is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Bencium's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Bencium?

A risk management plan has been developed to ensure that Bencium is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bencium, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Bencium

The marketing authorisation for Bencium was granted on 2019-05-21 in Sweden.

The full PAR for Bencium can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Bencium, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2019-05.