

Summary Public Assessment Report

Kollopan (calcium carbonate, cholecalciferol)

SE/H/2528/01-02/DC

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calcium carbonate, cholecalciferol

Film-coated tablet, 500 mg/400 IU, 500 mg/800 IU

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

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Kollopan and what is it used for?

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

The product is used to prevent and treat calcium and vitamin D₃ deficiency in elderly, and as an adjunct in the management of osteoporosis, when a risk of deficiency of calcium or vitamin D₃ is suspected.

How does Kollopan work?

The product contains calcium and vitamin D₃ which both are important components for the formation of bone. Vitamin D₃ regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

How is Kollopan used?

The pharmaceutical form is film-coated 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 in Sweden.

What benefits of Kollopan have been shown in studies?

As calcium carbonate, cholecalciferol, is a well-known substance, and its used to prevent and treat calcium and vitamin D₃ deficiency in elderly, and as an adjunct in the management of osteoporosis, when a risk of deficiency of calcium or vitamin D₃ is suspected.

The product is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of calcium carbonate, cholecalciferol, in the treatment of the above-mentioned indication.

What are the possible side effects from Kollopan?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Kollopan approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product 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, 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 Kollopan

The full PAR for Kollopan can be found on the following website: [MRI - Home](#). For more information about treatment with Kollopan, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-04.