

Summary Public Assessment Report

Calcium/Cholecalciferol Theramex (cholecalciferol, calcium carbonate)

SE/H/2512/001/DC

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cholecalciferol, calcium carbonate

Chewable tablet, 500 mg/1000 IU

This is a summary of the public assessment report (PAR) for Calcium/Cholecalciferol Theramex. 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 Calcium/Cholecalciferol Theramex 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 a combined calcium and vitamin D deficiency in adult patients at risk (e.g. postmenopausal women or the elderly)
- to correct a combined calcium and vitamin D deficiency in adults
- as a supplement to specific treatment of osteoporosis (brittle bones) of adult patients who are at risk of vitamin D and calcium deficiency.

Therapy is only advisable if a sufficient calcium and vitamin D supply cannot be achieved by nutrition and sunlight.

How does Calcium/Cholecalciferol Theramex work?

Calcium/Cholecalciferol Theramex contains calcium and cholecalciferol (vitamin D3), which are important substances in bone formation.

How is Calcium/Cholecalciferol Theramex used?

The pharmaceutical form 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 in Sweden.

What benefits of Calcium/Cholecalciferol Theramex have been shown in studies?

As calcium cholecalciferol and calcium carbonate is a well-known substance, and its use in the treatment:

- for the prevention and treatment of a combined vitamin D and calcium deficiency in adult risk patients (e.g. postmenopausal women or the elderly)
- as vitamin D and calcium supplement as an adjunct to specific osteoporosis treatment of adult patients who are at risk of vitamin D and calcium deficiency

Therapy is only advisable if a sufficient calcium and vitamin D supply cannot be achieved by nutrition and sunlight.

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

What are the possible side effects from Calcium/Cholecalciferol Theramex?

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 Calcium/Cholecalciferol Theramex 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 Calcium/Cholecalciferol Theramex?

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 Calcium/Cholecalciferol Theramex

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

This summary was last updated in 2025-01.