

Summary Public Assessment Report

Calcichew-D3 Melon, Calcichew-D3 Citron, Calcichew-D3 Melon (calcium carbonate/cholecalciferol)

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Summary Public Assessment Report

Calcichew-D₃ Citron, Calcichew-D₃ Melon

(calcium carbonate/cholecalciferol)

500 mg/400 IU, chewable tablet

500 mg/1000 IU, chewable tablet

500 mg/1000 IU, chewable tablet

This is a summary of the public assessment report (PAR) for Calcichew- D₃ Melon 500 mg/400 IU Chewable tablet, Calcichew- D₃ Citron 500 mg/1000 IU Chewable tablet, Calcichew- D₃ Melon 500 mg/1000 IU Chewable tablet. It explains how the products were assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use the products.

For practical information about using Calcichew- D₃ Melon 500 mg/400 IU Chewable tablet, Calcichew- D₃ Citron 500 mg/1000 IU Chewable tablet, Calcichew- D₃ Melon 500 mg/1000 IU Chewable tablet, patients should read the package leaflet or contact their doctor or pharmacist.

What are Calcichew-D₃ Citron and Calcichew-D₃ Melon and what are they used for?

Calcichew-D₃ Citron and Calcichew-D₃ Melon are indicated for prevention and treatment of vitamin D and calcium deficiency. Vitamin D and calcium supplement as an adjunct to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency.

How does Calcichew-D₃ Citron and Calcichew-D₃ Melon work?

Calcichew-D₃ Citron and Calcichew-D₃ Melon are chewable tablets containing calcium and vitamin D₃, which both are important substances in bone formation. Calcichew-D₃ Citron is used in the prevention and treatment of calcium and vitamin D deficiency, and as a supplement to specific treatment of osteoporosis.

How are Calcichew-D₃ Citron and Calcichew-D₃ Melon used?

The pharmaceutical form of Calcichew-D₃ Citron and Calcichew-D₃ Melon are chewable tablets 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 Calcichew-D₃ Citron and Calcichew-D₃ Melon have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Calcichew-D₃ Citron and Calcichew-D₃ Melon are effective used for the prevention and treatment of calcium and vitamin D deficiency, and as a supplement to specific treatment of osteoporosis.

What are the possible side effects of Calcichew-D₃ Citron and Calcichew-D₃ Melon?

For the full list of all side effects reported with Calcichew-D₃ Citron and Calcichew-D₃ Melon, see section 4 of the package leaflet.

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

Why are Calcichew-D₃ Citron and Calcichew-D₃ Melon approved?

The literature reviewed in this application confirms calcium and vitamin D supplementation as a well-established treatment for the current indication.

Therefore, the Medical Products Agency in Sweden decided that Calcichew-D₃ Citron and Calcichew-D₃ Melon'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 Calcichew-D₃ Citron and Calcichew-D₃ Melon?

A risk management plan has been developed to ensure that Calcichew-D₃ Citron and Calcichew-D₃ Melon 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 Calcichew-D₃ Citron and Calcichew-D₃ Melon, 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 Calcichew-D₃ Citron and Calcichew-D₃ Melon

The marketing authorisation for Calcichew-D₃ Citron and Calcichew-D₃ Melon was granted on 2015-05-27 in Sweden.

The full PAR for Calcichew-D₃ Citron and Calcichew-D₃ Melon can be found on the following website: <http://mri.medagencies.org/Human/>.

For more information about treatment with Calcichew-D₃ Citron and Calcichew-D₃ Melon, please read the package leaflet <https://lakemedelsverket.se/LMF/?q=calcichew> or contact your doctor or pharmacist.

This summary was last updated in 2015-05-27.