

Summary Public Assessment Report

Colecalciferol Internis (colecalciferol)

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(colecalciferol)

Oral Drops, solution, 2740 IU and 10000 IU.

This is a summary of the public assessment report (PAR) for Colecalciferol Internis. It explains how Colecalciferol Internis 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 Colecalciferol Internis.

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

What is Colecalciferol Internis and what is it used for?

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

Colecalciferol Internis is used to prevent and treat vitamin D3 deficiency in adults, adolescents and children with an identified risk of vitamin D3 deficiency.

Colecalciferol Internis can also be used as an adjunct to specific bone loss medication.

How does Colecalciferol Internis work?

Colecalciferol Internis contains the active ingredient colecalciferol (vitamin D₃):

Vitamin D₃ regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

How is Colecalciferol Internis used?

The pharmaceutical form of Colecalciferol Internis is Oral Drops, solution 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 Colecalciferol Internis have been shown in studies?

As colecalciferol is a well-known substance, and its use in the treatment and prevention of vitamin D3 deficiency in adults, adolescents and children with an identified risk of vitamin D3 deficiency and as an adjunct to specific bone loss medication, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of colecalciferol in the treatment and prevention of vitamin D3 deficiency in adults, adolescents and children with an identified risk of vitamin D3 deficiency and as an adjunct to specific bone loss medication.

What are the possible side effects of Colecalciferol Internis?

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

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

Why is Colecalciferol Internis approved?

The use of Colecalciferol Internis in the treatment and prevention of vitamin D3 deficiency in adults, adolescents and children with an identified risk of vitamin D3 deficiency and as an adjunct to specific bone loss medication 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 Colecalciferol Internis'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 Colecalciferol Internis?

A risk management plan has been developed to ensure that Colecalciferol Internis 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 Colecalciferol Internis, 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 Colecalciferol Internis

The marketing authorisation for Colecalciferol Internis was granted on 2017-05-22 in Sweden.

The full PAR for Colecalciferol Internis can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Colecalciferol Internis, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2017-05.