LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Divisun
(colecalciferol)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Divisun

(cholecalciferol)

Tablets, 1000 IU

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

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

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

Divisun contains vitamin D_3 and is used to treat vitamin D_3 deficiency in adults and adolescents.

Your doctor may prescribe Divisun as an adjunct to specific bone loss medication.

How does Divisun work?
Divisun contains vitamin D_3 which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

How is Divisun used?
The pharmaceutical form of Divisun is 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 Divisun have been shown in studies?
As cholecalciferol is a well-known substance, and its use in the treatments of vitamin D_3 deficiency in adults and adolescents are well established, the applicant presented data from the scientific literature.

The literature provided confirmed the efficacy and safety of cholecalciferol in the treatment of vitamin D_3 deficiency in adults and adolescents.

What are the possible side effects of Divisun?
For the full list of all side effects reported with Divisun, see section 4 of the package leaflet.

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

Why is Divisun approved?
The use of Divisun in the treatment of vitamin D deficiency in adults and adolescents 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 Divisun'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 Divisun?
A risk management plan has been developed to ensure that Divisun 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 Divisun, 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 Divisun
The marketing authorisation for Divisun was granted on 2015-12-04 in Sweden.

The full PAR for Divisun can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Divisun, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 201512.