

Summary Public Assessment Report

Bevitrio (cyanocobalamin, folic acid hydrate, pyridoxine hydrochloride)

SE/H/2159/01/DC

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Tablet, 0,5 mg/0,8 mg/3,0 mg

This is a summary of the public assessment report (PAR) for Bevitrio. 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 Bevitrio 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 for the prevention of symptom-causing deficiency of vitamin B6, vitamin B12 and folic acid caused by insufficient food intake or poor uptake of nutrients, particularly in the elderly.

How does Bevitrio work?

The product contains three B vitamins (folic acid, vitamin B₁₂ and vitamin B₆). B vitamins are important in maintaining the natural functions of the cells.

How is Bevitrio used?

The pharmaceutical form 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 in Sweden.

What benefits of Bevitrio have been shown in studies?

As cyanocobalamin, folic acid hydrate and pyridoxine hydrochloride are well-known substances, and their use in the prevention of symptom-causing deficiency of vitamin B6, vitamin B12 and folic acid caused by insufficient food intake or poor uptake of nutrients, particularly in the elderly, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of cyanocobalamin, folic acid hydrate and pyridoxine hydrochloride in the treatment of the above-mentioned indication.

What are the possible side effects from Bevitrio?

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 Bevitrio 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 Bevitrio?

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 Bevitrio

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

This summary was last updated in 2023-11.