LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Folsyra Vitabalans
(folic acid)

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Summary Public Assessment Report

Folsyra Vitabalans

(folic acid)

Tablet, 1 mg & 5 mg

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

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

What is Folsyra Vitabalans and what is it used for?

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

Folsyra Vitabalans is used in the treatment of folic acid deficiency states confirmed by blood test including testing of vitamin B12 levels.

How does Folsyra Vitabalans work?

Folic acid is a part of the coenzymes involved in certain transmethylation processes e.g. synthesis of deoxyribonucleic acid and ribonucleic acid. Folic acid is a component of the B group of vitamins and is necessary for the normal production and maturation of red blood cells. Folic acid deficiency is one of the causes of megaloblastic anaemia.

How is Folsyra Vitabalans used?

The pharmaceutical form of Folsyra Vitabalans 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 Folsyra Vitabalans have been shown in studies?

As Folic acid is a well-known substance, and its use in the treatment of Folate deficiency and deficiency prevention is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of Folic acid in the treatment of Folate deficiency and deficiency prevention.

What are the possible side effects of Folsyra Vitabalans?

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

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

Why is Folsyra Vitabalans approved?

The use of Folsyra Vitabalans in the treatment of Folate deficiency and deficiency prevention 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 Folsyra Vitabalans'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 Folsyra Vitabalans?

A risk management plan has been developed to ensure that Folsyra Vitabalans 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 Folsyra Vitabalans, 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 Folsyra Vitabalans

The marketing authorisation for Folsyra Vitabalans was granted on 2019-04-01 in Sweden.

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

This summary was last updated in 2019-04.