

Summary Public Assessment Report

Bladex (folic acid, anhydrous)

SE/H/2568/01-02DC

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Bladex
folic acid, anhydrous

tablet, 1 mg, 5 mg

This is a summary of the public assessment report (PAR) for Bladex. 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 Bladex 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 treatment of:

- folic acid deficiency states confirmed by blood test including testing of vitamin B12 levels.
- folic acid deficiency in patients taking medicines such as methotrexate (used to treat rheumatism).

the prevention of:

- neural tube defects in unborn babies (such as spina bifida, a birth defect of the spine), for women planning to become pregnant and when the risk of such defects is high.

How does Bladex work?

The product contains folic acid, a vitamin B required for normal blood formation.

Folic acid is a component of co-enzymes involved in certain transmethylation processes, such as DNA and RNA synthesis. Folic acid is one of the B 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 Bladex 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 Bladex have been shown in studies?

As folic acid is a well-known substance, and its use in:

- *Treatment of folate deficiency states confirmed by blood test including B12 status (ask your doctor or pharmacist about special warnings and precautions for use).*
- *During treatment with drugs that inhibit folate absorption or folate metabolism such as methotrexate.*

- *For the prevention of neural tube defects in the foetus for women planning a pregnancy and where the risk for neural tube defects in the foetus is elevated.*

Consideration should be given to national, official guidelines on the appropriate use of folic acid.

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 the above-mentioned indication.

What are the possible side effects from Bladex?

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 Bladex 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 Bladex?

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 Bladex

The full PAR for Bladex can be found on the following website: [MRI - Home](#). For more information about treatment with Bladex, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-06.