SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Folsyra Vitabalans 5 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg folic acid as folic acid hydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
A yellow or slightly orange, spotted, round, convex tablet with one-side score. Diameter of the tablet is 8 mm.

The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of folate deficiency states confirmed by blood test including vitamin B12 status (see section 4.4.).
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.

4.2 Posology and method of administration

Posology

Adults (including elderly)

Treatment of folate deficiency states confirmed by blood test including vitamin B12 status:
Remission treatment: 5 mg daily for about 2 weeks.
Up to 15 mg daily may be needed in malabsorption states.

The treatment effect should be monitored. For maintenance the dose might be reduced according to blood-test results. A product with lower strength should be selected in this case.

In drug induced folate deficiency:
5 mg weekly, dose to be taken on a different day than the folate-inhibiting drug.

Prevention of neural tube defects in the foetus for women planning a pregnancy:
5 mg daily started at least 4 weeks before conception and at least 12 weeks thereafter.

Paediatric population
[Product name] should not be used in children aged younger than 6 years.

In folate deficient megaloblastic anaemia:
Children and adolescents 6-17 years: 5 mg daily for 4 months.

Up to 15 mg daily may be needed in malabsorption states
The treatment effect should be monitored. For maintenance the dose might be reduced according to blood-test results. A product with lower strength should be selected in this case.

Special populations

No dosage adjustments are needed in the elderly.

No dosage adjustments are needed in patients with renal or hepatic impairment.

Method of administration
For oral use

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Patients with vitamin B_{12} deficiency should not be treated with folic acid unless administered with adequate amounts of hydroxocobalamin, as it can mask the condition but the subacute irreversible damage to the nervous system will continue. This can be detected analysing methylmalonic acid in plasma. The deficiency can be due to undiagnosed megaloblastic anaemia including in infancy, pernicious anaemia or macrocytic anaemia of unknown aetiology or other cause of cobalamin deficiency, including lifelong vegetarians.

Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication.

Caution should be exercised when administering folic acid to patients who may have folate dependent tumours.

4.5 Interaction with other medicinal products and other forms of interaction

- Antiepileptics –if folic acid supplements are given to treat folate deficiency caused by the use of antiepileptics (phenytoin, phenobarbital and primidone), the serum antiepileptic levels may fall, leading to decreased seizure control in some patients.
- Antibacterials –chloramphenicol, sulfonamides and trimethoprim may interfere with folate metabolism.
- Sulfasalazine –can reduce the absorption of folic acid.

4.6 Fertility, pregnancy and lactation

Pregnancy
Based on the human experience there are no known hazards to the use of folic acid in pregnancy. Harmful effects in the human foetus, mother or the pregnancy have not been reported following ingestion of folic acid. Please see also section 5.3.

Breastfeeding
Folic acid is actively excreted in human breast milk. No adverse effects have been observed in breast fed infants whose mothers were receiving folic acid.

Fertility
Animal studies to evaluate the effect on fertility have not been conducted.

4.7 Effects on ability to drive and use machines

[Product name] has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The frequency of undesirable effects in defined using the following conventions:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1000 to <1/100)
Rare (≥ 1/10 000 to <1/1000)
Very Rare (< 1/ 10 000)
Not known (cannot be estimated from the available data).

Immune system disorders
Rare: Allergic reactions
Not known: Anaphylactic reaction

Gastrointestinal disorders
Rare: Anorexia, nausea, abdominal distension and flatulence.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.*

4.9 Overdose

The acute toxicity is low. Normally, an overdose gives no symptoms. In exceptional circumstances, if symptoms should occur, treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antianemic preparations; Vitamin B12 and folic acid, ATC code: B03BB01

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.

5.2 Pharmacokinetic properties

Absorption
Folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part of the small intestine. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. The naturally occurring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestine to from 5-methyltetrahydrofolate (5MTHF). Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductases.

Distribution
Distribution is via portal circulation. 5MTHF from naturally occurring folate is extensively plasma bound. the principal storage site of folate is in the liver; it is also concentrated in the CSF. Folate is distributed into breast milk.

Biotransformation
Therapeutically given folic acid is converted into the metabolically active form 5MTHF in the plasma and liver. There is an enterohepatic circulation for folate.

Elimination
Folate metabolities are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine. Folic acid is removed by haemodialysis.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. Non-clinical studies on reproduction and development have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline
Starch, pregelatinized
Croscarmellose sodium
Sodium ascorbate
Silica colloidal anhydrous
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store in the original package in order to protect from light.

6.5 Nature and contents of container

30, 50 and 100 tablets in blister packs (PVC/PVdC/Al).
30, 50 and 100 tablets in bottles (container HD-PE plastic and closure LD-PE plastic).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vitabalans Oy

Varastokatu 8
FI-13500 Hämeenlinna
FINLAND
Tel: +358 (3) 615600
Fax: +358 (3) 6183130

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD month YYYY}

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

2021-03-01