

## Package leaflet: Information for the user

### Folsyra Vitabalans 5 mg tablets

folic acid

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

[To be completed nationally]

#### What is in this leaflet

1. What [product name] is and what it is used for
2. What you need to know before you take [product name]
3. How to use [product name]
4. Possible side effects
5. How to store [product name]
6. Contents of the pack and other information

#### 1. What [product name] is and what it is used for

[Product name] tablets contain folic acid, a vitamin B that is required for normal blood formation.

[Product name] may be used for:

##### The treatment of:

- folic acid deficiency states confirmed by blood test including testing of vitamin B12 levels.

##### The prevention of:

- folic acid deficiency in patients taking medicines such as methotrexate (used to treat rheuma).
- neural tube defects in unborn babies (such as spina bifida, a birth defect of the spine), for women planning to become pregnant.

#### 2. What you need to know before you take [product name]

##### Do not take [product name]:

- if you are allergic to folic acid or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions

Talk to your doctor or pharmacist before taking [product name]

- if you have cancer
- if you are diagnosed with vitamin B<sub>12</sub> deficiency or an anaemia of unknown cause.

### **Other medicines and [product name]**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because [product name] can affect the way some medicines work and some medicines can have an effect on [product name].

This especially applies to the following medicines:

- phenytoin, phenobarbital and primidone used to treat epileptic attacks
- chloramphenicol, sulfonamides and trimethoprim used to treat infections
- sulfasalazine used to treat inflammatory bowel diseases (ulcerative colitis, Crohn's disease) or inflammatory joint disease (rheumatoid arthritis).

### **Use in children**

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

### **Pregnancy and breast-feeding**

[Product name] can be used during pregnancy and breast-feeding.

### **Driving and using machines**

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

## **3. How to take [product name]**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.  
[To be completed nationally]

### **The recommended dose is:**

#### Adults (including elderly)

##### *Treatment of folic acid deficiency:*

5 mg daily for about 2 weeks. Up to 15 mg daily may be needed in abnormal absorption across the gastrointestinal tract.

Maintenance treatment: The dose is determined by your doctor according to blood-test results.

##### *In drug induced folic acid deficiency:*

5 mg weekly. The dose should be taken on a different day than the folate-inhibiting drug (such as methotrexate).

##### *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.

### **Use in children and adolescents**

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

#### *In folic acid deficient megaloblastic anaemia:*

Children and adolescents 6-17 years: 5 mg daily for 4 months. Up to 15 mg daily may be needed in abnormal absorption across the gastrointestinal tract. Maintenance treatment: The dose is determined by your doctor according to blood-test results.

### Method of administration

For oral use  
The tablet can be divided into equal doses.

**If you take more [product name] than you should**

If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

**If you forget to take [product name]**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking [product name]**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you notice the following serious side effect, stop taking [product name] and contact your doctor or hospital immediately:**

*Not known (frequency cannot be estimated from the available data)*

- severe allergic reaction (anaphylactic reaction): itching, skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Other side effects:

*Rare* (may affect up to 1 in 1000 users):

- an allergic reaction: itching, skin rash.
- nausea, loss of appetite, a feeling of fullness and wind.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#).\* By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store [product name]**

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the carton, bottle and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

**What [product name] contains**

- The active substance is folic acid. Each tablet contains 5 mg folic acid as folic acid hydrate.

- The other ingredients are: microcrystalline cellulose, pregelatinised starch, croscarmellose sodium, sodium ascorbate, silica colloidal anhydrous, magnesium stearate.

#### **What [product name] looks like and contents of the pack**

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

*Pack sizes:*

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

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Vitabalans Oy  
Varastokatu 8  
13500 Hämeenlinna  
Finland  
Tel: +358 (3) 615600  
Fax: +358 (3) 6183130

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Folic Acid Vitabalans (, Estonia, Finland, Latvia, Lithuania)  
Folsyre Vitabalans (Denmark)  
Folsäure Vitabalans (Germany)  
Folsav Vitabalans (Hungary)  
Folna kislina Vitabalans (Slovenia)  
Folsyra Vitabalans (Sweden)

**This leaflet was last revised in 2019-01-24.**