

## Information leaflet: Information for the user

### BALFOLIC 400 microgram tablets

#### Folic acid

**Read all of this leaflet carefully before you start taking this medicine as 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. You must not give it to others. The medicine can harm them even if they have the same signs of illness.
- 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.

#### **What this leaflet contains:**

1. What BALFOLIC is and what it is used for
2. What you need to know before taking BALFOLIC
3. How to take BALFOLIC
4. Possible side effects
5. How to store BALFOLIC
6. Package Contents and Other Information

#### **1. What BALFOLIC is and what it is used for**

Folic acid is a vitamin and is necessary for the production of new cells in the body.

To stay healthy, you need a regular supply of folic acid.

Especially women who are planning to become pregnant and pregnant women need a good supply of folic acid as it will be used in the development of the baby.

BALFOLIC is useful to help prevent babies from being born with neural tube defects eg. spina bifida (rare malformation involving the lower end of the spine, which can lead to hernias in the spinal cord, bowel, urinary incontinence, impaired motility and lower limb sensitivity).

## **2. What you need to know before taking BALFOLIC**

### **Do not take BALFOLIC:**

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

### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking BALFOLIC:

- if you are a woman who has previously given birth to a baby (or miscarried a fetus) with neural tube defects;
- if you are taking antiepileptics: carbamazepine or valproic acid;
- if you have a family history of neural tube defects;
- if you are taking folic acid antagonists (methotrexate, sulfasalazine);
- if you suffer from pernicious anemia, as folic acid can mask the diagnosis by relieving the hematological manifestations of the disease, while allowing the neurological complications to evolve.

In the above situations, it may be necessary to take a dose of folic acid higher than the dose present in a BALFOLIC tablet.

It should be noted that if you are using folic acid antagonists it is more appropriate to use folinic acid rather than higher doses of folic acid.

### **Other medicines and BALFOLIC:**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Tell your doctor if you are taking or have recently taken any of the following medicines:

- antiepileptics (phenobarbital, phenytoin or primidone);
- folic acid antagonists (methotrexate, sulfasalazine).

### **BALFOLIC with food, drink and alcohol:**

Concomitant use of BALFOLIC with tea, including green tea, should be avoided.

**Pregnancy, breastfeeding and fertility:**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

There are no data available on the effect of the medicine on the ability to drive. However, no effect is expected.

**BALFOLIC contains lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. How to take BALFOLIC**

Always take this medicine exactly as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you have any questions.

The usual dose of BALFOLIC is one tablet a day from 1 month before conception until 3 months of pregnancy.

In case of inadequate intake of folic acid through food, your doctor may decide to double the daily dose.

You should take BALFOLIC orally before meals.

This dosage may not be adequate if you have previously given birth to babies with neural tube defects.

**If you take more BALFOLIC than you should**

Doses much higher than those present in BALFOLIC are unlikely to be harmful.

**If you forget to take BALFOLIC**

Do not take a double dose to make up for a forgotten tablet.

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.

The following side effects have been reported and are rare (may affect 1 to 10 users in 10,000).

Allergic reactions such as:

- erythema;
- itch;
- hives.

With higher doses than those present in BALFOLIC, you may experience gastrointestinal disturbances (nausea, abdominal disturbances, flatulence), irritability and insomnia.

#### **Communicating side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you will help to provide more information about the safety of this medicine.

INFARMED, I.P.

Medicines Risk Management Department  
Parque da Saúde de Lisboa, Av. Brasil 53  
1749-004 Lisbon

Tel: +351 21 798 73 73

Medicine Line: 800222444 (free)

Fax: + 351 21 798 73 97

Website: <http://extranet.infarmed.pt/page.seram.frontoffice.seramhomepage>

E-mail: [pharmacovigilancia@infarmed.pt](mailto:pharmacovigilancia@infarmed.pt)

#### **5. How to store BALFOLIC**

Do not store above 30°C.

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

Do not use this medicine after the expiry date which is stated on the blister and carton after "EXP.". The shelf-life period corresponds to the last day of the indicated month.

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

## **6. Package Contents and Other Information**

### **BALFOLIC composition**

- The active substance is folic acid.

Each BALFOLIC tablet contains 400 micrograms of folic acid.

- The other ingredients are sodium carboxymethyl starch (Type A), microcrystalline cellulose, lactose monohydrate and magnesium stearate.

### **What BALFOLIC looks like and contents of the pack**

Pale yellow round tablets.

BALFOLIC is presented in a white PVC/PE/PVDC/Aluminium blister in a cardboard box with 20, 60 or 120 tablets.

It is possible that not all presentations are marketed.

### **Marketing Authorization Holder and Manufacturer**

#### **Marketing Authorization Holder**

Baldacci Portugal, S.A.

Rua Cândido de Figueiredo, 84 B

1549-005 Lisbon

Portugal

#### **Manufacturer**

Laboratori Baldacci SpA

Via San Michele degli Scalzi 73

56100 PISA

Italy

**This leaflet was last revised in 13.10.2017**