

Package leaflet: Information for the patient

Bladex 1 mg tablets

Bladex 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.

What is in this leaflet

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

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

[Invented name] contains folic acid, a vitamin B required for normal blood formation.

[Invented name] 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.

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

Do not take [Invented 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 [Invented name].

Do not use this medicine without your doctor's prescription, as folic acid can mask the lack of vitamin B₁₂.

[Invented name] should be used with caution in certain tumor diseases. Consult your doctor if you are treated for any tumor disease before you start taking [Invented name].

Other medicines and [Invented name]

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

The following medicines can affect or may be affected by treatment with [Invented name]:

- Phenytoin, phenobarbital, primidone and possibly carbamazepine (used to control epileptic fits)
- Fluorouracil, glucarpidase, methotrexate, capecitabine (used to treat certain tumours)
- Some antibiotics, e.g. trimethoprim, sulfonamides
- Sulfasalazine (used to treat the inflammatory bowel conditions, like ulcerative colitis and Crohn's disease)
- Pyrimethamine (used to treat toxoplasmosis - infection by a parasite)
- Triamterene (used to treat hypertension and oedema - accumulation of fluid in the body)
- Medicines against tuberculosis
- Oral contraceptives
- Anti-malaria medicinal products

[Invented name] with alcohol

Alcohol may lower the folic acid level in your blood.

Pregnancy and breast-feeding

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.

No harmful effects have been observed when using folic acid during pregnancy.

Folic acid is excreted into breast milk; however, it is usually compatible with breast-feeding.

Driving and using machines

This medicine is not known to affect the ability to drive or to use machines.

[Invented name] contains lactose and sucrose

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 [Invented name]

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

Your doctor will decide the correct dose for you and will advise you how long to take this medicine for.

Adults (including elderly)

Treatment of folic acid deficiency

The recommended dose is 1 to 5 mg daily, which may be increased. Your doctor will prescribe an appropriate dose.

In drug induced folic acid deficiency (e.g. patients receiving methotrexate)

The recommended dose is 1 mg daily or 5 mg once weekly. Your doctor will prescribe an appropriate dose. The dose should be taken 24 hours after methotrexate therapy.

Pregnant women and women who want to get pregnant

5 mg daily started at least 4 weeks before conception and at least 12 weeks thereafter. [Invented name] should be taken according to doctor's instructions.

Use in children and adolescents

[Invented name] 1 mg tablets can be used in children and adolescents aged 1–18 years.

[Invented name] 5 mg tablets can be used in children and adolescents aged 6–18 years.

To treat folic acid deficiency anaemia

The recommended dose for children and adolescents is 0.5–1 mg daily, which may be increased. Your doctor will prescribe an appropriate dose. The doctor will check the blood regularly to determine the folate level.

Method of administration

Oral use.

The tablets can be taken independent of meals with a glass of liquid. The tablet can be divided into equal doses.

For patients who are unable to swallow tablets, the tablet may be crushed and mixed with food or dissolved in water, immediately before you take it.

Duration of treatment

The duration of treatment depends on the cause of the folic acid deficiency and on the success of treatment.

If you take more [Invented name] than you should

In general, it is unlikely that this medicine will cause any harm if you take more medicine than you should or if a child has taken this medicine by accident, so usually no medical intervention is necessary. If you or a child has taken many tablets or if you are at all concerned, contact your doctor or the nearest hospital for advice.

If you forget to take [Invented 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 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 [Invented 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 1,000 people)

- Mild allergic reaction
- Nausea (feeling sick), vomiting (being sick), diarrhoea, flatulence
- Rash, itching, hives, swelling of the face, lips, tongue or throat (facial angioedema)

Reporting of 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 via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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 carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. This medicine does not require any special temperature storage conditions.

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 [Invented name] contains

- The active substance is folic acid. Each tablet contains folic acid hydrate equivalent to 1 mg or 5 mg folic acid.
- The other ingredients are lactose monohydrate, pregelatinised starch, macrogol, stearic acid (E 570), sucrose, magnesium stearate (E 470b).

What [Invented name] looks like and contents of the pack

[Invented name] 1 mg tablets are light yellow or light yellow orange speckled, round and biconvex tablet with breaking line on one side with a diameter of about 7.0 mm and thickness of about 2.75 mm

[Invented name] 5 mg tablets are yellow or yellow orange speckled, round and biconvex tablet with breaking line on one side with a diameter of about 7.0 mm and thickness of about 2.75 mm

[Invented name] 1 mg and 5 mg are available in blister packs with 12, 20, 28, 30, 40, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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