

PATIENT INFORMATION LEAFLET

FOLAS 5 mg Tablets

For oral use.

- **Active substance(s):** Each tablet contains folic acid hydrate equivalent to 5 mg folic acid.
- **Excipient(s):** Lactose monohydrate (derived from cow's milk), pregelatinized starch, sodium starch glycolate, colloidal silicon dioxide, talc, and magnesium stearate.

Read this PATIENT INFORMATION LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. *What FOLAS is and what it is used for?*
2. *What you need to know before you use FOLAS?*
3. *How to use FOLAS?*
4. *Possible side effects*
5. *How to store FOLAS?*

1. What FOLAS is and what it is used for?

FOLAS is a yellow, round, flat tablet with notch on one side that may contain red spots. It contains folic acid, a type of B vitamin. FOLAS is used in the treatment of the following diseases related to folic acid deficiency:

- Some problems with the absorption of nutrients from the digestive tract (tropical or non-tropical sprue)
- Anemia caused by diet (anemias)
- A type of anemia due to folic acid deficiency in pregnant women, infants, or children (megaloblastic anemia)

2. What you need to know before you use FOLAS?

DO NOT use FOLAS.

If;

- you are allergic or intolerant to the active substance folic acid hydrate or other ingredients in FOLAS.
- you have cobalamin deficiency or pernicious anemia or have been vegetarian for a long time (FOLAS must be used together with another medicine)
- you have malignant cancer.
- you have been told by your doctor that you have an intolerance to certain sugars

Warnings and precautions

FOLAS is not used alone for types of anemia such as pernicious anemia and megaloblastic anemia, a vitamin B12 deficiency. In this case, your doctor will give you vitamin B12 in addition. Do not use FOLAS alone in these diseases.

If you are taking antibiotics, some blood tests for folic acid may give false results. You should tell your doctor that you are taking antibiotics before having a folic acid test.

Use FOLAS with caution if you are being treated with a group of medicines known as folate antagonists and if you have a tumor.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

FOLAS with food and drink

You can take FOLAS before or after meals. Take your medicine with plenty of water.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

FOLAS is used during pregnancy. It does not harm the baby when used during pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

You can breastfeed your baby while using FOLAS. No harmful effects have been observed in babies breastfed by mothers using FOLAS.

Driving and using machines

FOLAS has no known effect on driving and using machines.

Important information about some of the excipients of FOLAS

FOLAS contains lactose monohydrate as an excipient. If you have been previously told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicinal product.

Other medicines and FOLAS

Caution should be exercised when using the following medicines together with FOLAS:

- Corticosteroid group drugs, painkillers, drugs that prevent involuntary muscle movements (such as epilepsy drugs), drugs containing the hormone estrogen, drugs containing the substance hydantoin: If you have been taking these drugs for a long time, you may have an increased need for folic acid. In this case, your doctor may change your dose.
- Epilepsy medicines (such as phenytoin, phenobarbital, and primidone): When FOLAS is used together with these drugs, the effect of the epilepsy medicine may decrease.

- Drugs containing methotrexate, primethamine, triamterene or trimethoprim: These drugs counteract the effect of FOLAS.
- Drugs containing sulfonamide antibiotics such as sulfasalazine: These drugs interfere with the absorption of folic acid and therefore reduce its effect.
- Drugs containing chloramphenicol and co-trimoxazole: These drugs can reduce the effect of FOLAS.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use FOLAS?

Instructions for use and dosage/frequency of administration:

FOLAS is used 1 tablet (5 mg) daily for 4 months for the treatment of megaloblastic anemia due to folic acid deficiency.

It can be given up to 3 tablets (15 mg) daily in cases of malabsorption of nutrients.

In cases of anemia, such as Mediterranean anemia or sickle cell anemia, one tablet (5 mg) may be used daily or weekly. Your doctor will decide your dose.

Route of administration and method:

FOLAS is administered orally. Take your medicine before or after meals, with plenty of water.

Different age groups:

Use in children:

In children, a more suitable form of medication other than tablets may be used.

Treatment of megaloblastic anemia due to folic acid deficiency:

In children aged 1 to 18 years: 5 mg (1 tablet) daily for 4 months; then 5 mg (1 tablet) every 1 to 7 days.

Use in elderly:

No special dose adjustment is required for elderly patients. Your doctor will decide your dose.

Special cases of use:

Renal/Hepatic failure:

In kidney patients undergoing dialysis, one tablet can be taken daily or weekly. If you have kidney disease, you should talk to your doctor before taking FOLAS.

If you have impression that the effect FOLAS is very strong or weak, tell a doctor or pharmacist.

If you use more FOLAS than you should:

If you use more FOLAS than you should, tell your doctor or pharmacist.

If you forget to use FOLAS:

If you have missed the time to take your medicine, take it as soon as you remember. If it is almost time for your next dose, wait and take the next dose and then continue taking your medicine as

usual.

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

If you stop using FOLAS:

You should take your medicine for as long as your doctor tells you.

4. Possible side effects

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

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

If you notice any of the followings stop taking FOLAS and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Symptoms of a severe allergic reaction such as sudden wheezing, difficulty breathing, swelling of the eyelids, face or lips, rash or itching (especially all over the body), redness.

These are all very serious side effects.

If you have any of these, you are allergic to FOLAS. You may need urgent medical attention or hospitalization.

All of these very serious side effects are rare.

If you notice any of the followings immediately inform your doctor or go to the nearest emergency department:

- Changes in sleep patterns, irritable mood, depression
- Nausea, decreased or loss of appetite, feeling of abdominal distension.

These are all serious side effects. You may need urgent medical attention.

If you experience any one of the followings tell your doctor:

- Flatulence

These are mild side effects of FOLAS.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store FOLAS?

Keep this medicine out of the sight and reach of children in its original packaging.

Store at room temperature below 25°C, protected from light in the original packaging.

Use in accordance with expiry date.

Do not use FOLAS after the expiry date which is stated on the package.

Do not use FOLAS if you notice any defects in the product and/or its packaging.

Marketing Authorization Holder:

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