Package leaflet: Information for the user

Foliumzuur ratiopharm 5 mg, tabletten
folic acid hydrate

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 <PRODUCT NAME> is and what it is used for
2. What you need to know before you take <PRODUCT NAME>
3. How to take <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> contains the active ingredient folic acid hydrate.

Folic acid is a medicine belonging to the vitamin B group.

<PRODUCT NAME> is used for:
- Treatment of folic acid deficiency, including a condition called megaloblastic anaemia caused by folic acid deficiency. This can be caused by poor diet, poor absorption of food such as in coeliac disease or sprue, during pregnancy or due to breakdown of red blood cells.
- Prevention of folic acid deficiency caused by certain medicines, for example phenytoin, phenobarbital and primidone, which are used to treat epilepsy.
- Prevention of foetal neural tube defects (such as spina bifida) in women who are planning a pregnancy and are at risk of having a child with this defect.

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). An allergic reaction may include skin rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- if you have been diagnosed with pernicious anaemia not treated or treated insufficiently with vitamin B_{12} or megaloblastic anaemia of unknown origin.

Warnings and precautions
This medicine is for use in pregnant women if one of the following situations is applicable:
- if you have a known folic acid deficiency;
- if you have had a pregnancy (whether carried to term or not) in which neural tube defects were diagnosed in the infant;
- if you use anti-epileptic medicines (e.g. carbamazepine or valproic acid);
- if someone in your family has had neural tube defects;

- if you use folic acid antagonists (e.g. sulfasalazine, methotrexate);
- if you have type I or II diabetes mellitus.

This medicine may also be prescribed to pregnant women in other situations.

Talk to your doctor or pharmacist before taking <PRODUCT NAME>
– if you have a malignant tumour, as folic acid should generally not be taken by cancer patients;
– if you suffer from vitamin B_{12} deficiency associated with certain forms of anaemia (megaloblastic anaemia, pernicious anaemia), since this medicine, if administered alone, could worsen or provoke the appearance of symptoms of your disease which can lead to serious neurological damage;
– if you are taking anti-epileptic medicines (see section "Other medicines and <PRODUCT NAME>").

Antibiotics may alter the result of some laboratory tests for the concentrations of folic acid.

Other medicines and <PRODUCT NAME>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is particularly in regards to the following medicines:
– medicines for treating epileptic fits, such as phenytoin, phenobarbital and primidone, as this medicine could reduce their effect;
– methotrexate (used to treat certain forms of cancer), sulfasalazine (used as an anti-inflammatory against ulcerative colitis, Crohn's disease or rheumatoid arthritis) and pyrimethamine (used to treat infections caused by parasites, such as toxoplasmosis and isosporiasis), as they may reduce the effectiveness of this medicine;
– paracetamol, aspirin, ibuprofen and other anti-inflammatory medicines, if taken at very high doses, as they may reduce the efficacy of this medicine;
– trimethoprim or sulfonamides, alone or in combination, such as with cotrimoxazole (antibacterial medicine), as they may reduce the effect of this medicine;
– chloramphenicol as its use may reduce the efficacy of supplemental folic acid;
– cimetidine and other antacids (used to treat heartburn and gastric hyperacidity), but also cholestyramine and colestipol (used to treat excessively high blood cholesterol levels), as they may reduce the activity of this medicine;
– antituberculosis medicines, alcohol and oral contraceptives, as they may reduce the efficacy of this medicine;
– green and black tea as they should be avoided during folic acid treatment;
– fluorouracil (used to treat some tumours), as toxicity reactions may arise.

<PRODUCT NAME> with food and drink
Do not take this medicine with alcohol. Alcohol may reduce the effectiveness of this medicine.

Pregnancy, breast-feeding and fertility
This medicine can be used safely during pregnancy and is often useful.
Folic acid is excreted in breast milk.

Driving and using machines
<PRODUCT NAME> has no or negligible influence on the ability to drive and use machines.

<PRODUCT NAME> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

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.

Oral use:
– swallow the tablet whole with water, at the same time every day, on an empty stomach.
– take this medicine for the period of time indicated by your doctor.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Adult patients (including elderly patients)

Folic acid deficiency
The folic acid deficiency should be confirmed by your doctor by a blood test.

The recommended dose is: 5 mg per day for 4 months. In some cases your doctor may increase the dose up to 15 mg per day.

To treat folic acid deficiency during pregnancy the recommended dose is: 5 mg per day continuously until the end of the pregnancy.

To treat less severe folic acid deficiency, a product with lower strength might be prescribed by your doctor.

Drug induced folic acid deficiency
The recommended dose is: 5 mg per day for 4 months. In some cases, your doctor may increase the dose up to 15 mg per day.

Prevention of foetal neural tube defects in women who are planning a pregnancy and are known to have risk factors that can lead to such defects
The recommended dose is: 5 mg per day to be started at least 3 months before conceiving and to be continued throughout the first trimester of the pregnancy.

<PRODUCT NAME> is not effective in preventing the onset of neural tube developmental defects if the treatment is started after the fourth week of pregnancy.

Use in children and adolescents
<PRODUCT NAME> should not be used in children under 6 years of age because the tablets do not contain a dose suitable for children in this age group.
For children aged under 6 years, see other folic acid formulations on the market.

Folic acid deficiency
In children and adolescents 6-18 years of ages, the recommended dose is: 5 mg per day for 4 months.

Drug induced folic acid deficiency
In children and adolescents 6-18 years of age, the recommended dose is: 5 mg per day for 4 months.

Prevention of foetal neural tube defects
<PRODUCT NAME> is not for use in women before menarche.

If you take more <PRODUCT NAME> than you should
<PRODUCT NAME> is unlikely to damage to your health in any way.
Folic acid overdose has been observed after chronic administration of very high doses (over 15 mg folic acid per day for more than 4 weeks), with following manifested symptoms: bitter taste, loss of appetite, nausea, flatulence, nightmares, agitation and depression.

If you inadvertently take an overdose of <PRODUCT NAME>, no special actions are required.

If you forget to take <PRODUCT NAME>
If you forget to take a tablet, take one as soon as you remember unless it is almost time to take your next tablet. Do not take a double dose to make up for a forgotten tablet.
If the doctor has prescribed you more than one tablet per day, take the remaining tablets at the correct time.

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.
Folic acid is generally well tolerated. Gastrointestinal disturbances and hypersensitivity reactions have been reported rarely.

The following side effects have also been reported:

Not known: frequency cannot be estimated from the available data:
- Fever, hypersensitivity and serious allergic reaction (anaphylactic reaction).
- Sleep disorders, agitation and depression.*
- Bitter taste, flatulence, loss of appetite, nausea.*
- Rash, itching, redness of the skin, hives, sudden facial swelling.

*Effects observed in patients treated with higher doses than those contained in this medicine.

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 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.

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.

This medicine does not require any special 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 <PRODUCT NAME> contains

- The active substance is folic acid hydrate. Each tablet contains 5 mg of folic acid hydrate.
- The other excipients are hydroxypropylcellulose, croscarmellose sodium (see section 2 "<PRODUCT NAME> contains sodium"), microcrystalline cellulose, silica colloidal anhydrous and stearic acid 50.

What <PRODUCT NAME> looks like and contents of the pack

<PRODUCT NAME> tablets are yellowish to orange in colour, round, convex, bevelled-edge tablets of 7 mm in diameter, debossed ‘5’ on one side’ and with a score line on the other side.

<PRODUCT NAME> is available in PVC-PVDC/Al blister packs of 20, 28, 60 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Ratiopharm GmbH
Graf-Arco-Strasse 3
89079 Ulm
Duitsland

Manufacturer

SANTA SA
Str. Panselelor nr. 25, 27, 29
Brasov, jud.
cod 500419 Brasov
Roemenië

In het register ingeschreven onder:
RVG 131255

This medicine is authorised in the Member States of the European Economic Area under the following names:

Nederland	Foliumzuur ratiopharm 5 mg, tabletten
Italië	Acido Folico Teva

Deze bijsluiter is voor het laatst goedgekeurd in november 2024.