

PACKAGE LEAFLET INFORMATION FOR THE USER

FOLIFER, film coated tablets

Iron (as dried ferrous sulfate) 90 mg; Folic acid 1 mg

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT FOLIFER IS AND WHAT IT IS USED FOR

Pharmacotherapeutic Group: Antianemic Preparations. ATC Code B03A D03.

FOLIFER is a medicinal product that contains bivalent iron and folic acid, two essential antianemic factors in the successive phases of the haematopoiesis.

FOLIFER is indicated in the prophylaxis and treatment of deficiency states of iron and folic acid during pregnancy, lactation and puerperium.

2. BEFORE YOU TAKE FOLIFER

Do not take FOLIFER

- if you are allergic (hypersensitive) to iron, folic acid or any of the other ingredients of FOLIFER;
- if you have excess iron (e.g. haemochromatosis, haemosiderosis);
- if you have vitamin B12 deficiency (megaloblastic anaemia).
- if you have undergone repeated blood transfusions
- if you are having concomitant parenteral iron therapy

Take special care with FOLIFER

- if you have an acute gastrointestinal disease.
- if you are planning to become pregnant, FOLIFER should not be used to prevent neuronal tube defects.
- if you have vitamin B12 deficiency or pernicious anaemia.
- if you have intolerance to some sugars, namely lactose.
- when taking FOLIFER, stools become dark green or black. This effect is harmless.

- due to the risk of mouth ulceration and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth but swallowed whole with water. If you cannot follow this instruction or have difficulty swallowing, please contact your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking some antibiotics, such as tetracyclines or quinolones, you shall take Folifer at least two or three hours before or after the antibiotic.

If you are taking medicines containing thyroxine or penicillamine, FOLIFER may reduce the effect of these medicines.

If you are taking antacids, calcium supplements or medicines containing bicarbonate, carbonate, oxalates, or phosphates, iron absorption may be reduced. If you are taking medicines containing ascorbic acid (vitamin C) iron absorption may be altered.

If you are taking medicines containing chloranphenicol, they may reduce folic acid absorption.

If you are taking medicines containing methyldopa, FOLIFER may reduce its hypotensive effect.

If you are an epileptic patient being treated with phenytoin, Folifer may cause an increased frequency of seizures.

Taking FOLIFER with food and drink

Swallow the tablet unbroken, with a small amount of water or fruit juice (avoid milk), preferably taken on an empty stomach. However, in case of gastric upset, FOLIFER should be taken during meals (lunch or dinner). Many foods such as tea, coffee, milk and cereals may reduce the absorption of iron.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The use of FOLIFER during pregnancy is safe and is indeed indicated in that situation as pregnancy may cause iron and folic acid deficiency, and therefore such prevention is recommended.

This association shall not be used for the prophylaxis of neural tube defects in women who plan to become pregnant.

The use of iron and folic acid, the active substances of FOLIFER, during lactation is safe, although folic acid is excreted in mother's milk. This is a physiological situation in which deficiency of both nutrients may occur, and it is therefore, indicated for this prevention.

Driving and using machines

The effects of FOLIFER on the ability to drive and use machines are nil or insignificant.

Important information about some of the ingredients of FOLIFER

FOLIFER contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE FOLIFER

Always take FOLIFER exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 1 tablet daily.

Swallow the tablet whole with water. Do not suck, chew or keep the tablet in your mouth.

If you take more FOLIFER than you should

Overdose of FOLIFER occurs only rarely in adults, but it can occur in children. Toxicity due to an excessive intake is caused by iron overdose.

If a large amount of FOLIFER is taken all at once, contact immediately the nearest Health Care Unit. You may feel gastric or other disturbances that may require urgent attention and treatment.

If you forget to take FOLIFER

In the event of a dose of FOLIFER being missed, skip the missed dose and go back to your regular dosing schedule, in accordance with the physician's prescription.

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

If you stop taking FOLIFER

FOLIFER must be taken to the end of the prescribed course of treatment. Do not stop the treatment if you feel better. If you have any doubts, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FOLIFER can have side effects, although not everybody gets them.

Commonly reported side effects are of gastrointestinal type, especially abdominal pain, heartburn, nausea, vomiting, constipation or diarrhoea. Stools commonly become dark green or black due to excretion of iron. This effect is harmless.

Rarely, allergic reactions such as erythema, skin rash, itching and breathing difficulties may occur.

Not known (frequency cannot be estimated from the available data): mouth ulceration (in case of incorrect use, when tablets are chewed, sucked or left in the mouth), severe allergic reaction (anaphylactic reaction). Elderly patients and patients with difficulty swallowing may also be at risk of ulceration of the throat, oesophagus (the tube that connects your mouth with your stomach) or bronchus (the major air passages of the lungs) if the tablet enters the airways.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FOLIFER

Keep out of the reach and sight of children.

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

This medicine does not require any special storage conditions. Store in the original package.

6. FURTHER INFORMATION**What FOLIFER contains**

The active substances are iron (as dried ferrous sulfate) 90 mg and folic acid 1 mg, per tablet.

The other ingredients are: Lactose mono-hydrate; Maize starch; Povidone; Talc; Citric acid, anhydrous; Magnesium Stearate; Eudragit RLPO[®], Opadry OY-S-33019[®]

What FOLIFER looks like and contents of the pack:

FOLIFER: salmon, film coated tablets, circular and biconvex, engraved "Bial" on one side and "FF" on the other.

FOLIFER, film coated tablets, boxes of 20 or 60.

Marketing Authorisation Holder and Manufacturer:

BIAL - Portela & C^a, S.A.,

À Av. da Siderurgia Nacional

4745-457 S. Mamede do Coronado-Portugal

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