PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

FERCEFOL® coated tablets
Ferrous fumarate, Vitamin C, Folic acid
FERCEFOL® syrup - FERCEFOL® Oral solution
Iron (III)-hydroxide polymaltose, Vitamin C, Folic acid

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 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 start to experience any serious side effects, or if you notice any side effects not mentioned in this leaflet, talk to your doctor or pharmacist.

What is in this leaflet?

1. WHAT FERCEFOL® IS AND WHAT IT IS USED FOR?

FERCEFOL® coated tablets: box with 30 coated tablets in aluminium strips of 10 coated tablets each.
FERCEFOL® syrup: 150 ml bottle.
FERCEFOL® oral solution: stick pack of 10 ml, box of 20 stick pack.
Pharmacotherapeutic group: Iron in other combinations - various combinations. ATC code: B03AE10.
FERCEFOL® is an antianaemic preparation based on a combination of an iron salt, folic acid and vitamin C.
Iron is an essential component of the body. It is necessary for the formation of haemoglobin and for oxidation processes in living tissues.
Folic acid has an important role as a coenzyme in various metabolic processes, including the maturation and regeneration of blood cells.
Vitamin C increases the absorption of iron.

Therapeutic indications:
- curative treatment of iron deficiency anaemia (minimum 4 to 6 months of treatment, in combination with aetiological treatment),
- preventive treatment of iron deficiency in vulnerable subjects: pregnant women, unbalanced diets (elderly, vegetarians, vegans, anorexia nervosa), chronic non-curable bleeding disorders,
- megaloblastic anaemia due to folic acid deficiency,
- chronic intestinal absorption disorders (malabsorption, celiac disease, major bowel resection),
- inadequate intake of folate: malnutrition, chronic alcoholism.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FERCEFOL®?

If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

Do not take FERCEFOL® :
- If you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6);
- If you have too much iron in your body (e.g. haemochromatosis or haemosiderosis);
- If you have problems with the absorption of iron (e.g. thalassaemia);

- If you have an anaemia that is not caused by iron deficiency (e.g. haemolytic anaemia [due to haemolysis, with the anomalous destruction of red blood cells] or megaloblastic anaemia [a blood disorder in which the red blood cells are very large]);
- Isolated use in the case of vitamin B12 deficiency.

In case of doubt, it is essential to ask the advice of your doctor or pharmacist.

Warnings and precautions

Ask your doctor or pharmacist before taking FERCEFOL®.
Anaemia can also be caused by infections and tumors. Iron cannot be used until the primary disease is cured. Talk to your doctor if you have a chronic infection or tumor.
During treatment with FERCEFOL®, stool can become very dark, which is not serious.
Iron preparations can cause poisoning, especially in children. Talk to your doctor if you are taking iron supplements.

Other medicines and FERCEFOL®

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

- You should not take iron orally and intravenously (by infusion into a vein) at the same time. The absorption of iron taken orally is significantly reduced with simultaneous use.
- No changes in effect are likely to occur when taken together with other medicinal products.
- The absorption of iron is decreased in the presence of antacid medication.
- Concomitant administration of tetracycline leads to a reduction in resorption (a 2 to 3 hour interval between administrations is essential).
- The bioavailability and action of levodopa, methyldopa, penicillamine and fluoroquinolones such as ciprofloxacin and ofloxacin are also reduced.
- Some food constituents such as phytates (present in cereals) or phosphates can form insoluble compounds with iron.
- Zinc salts can reduce the absorption of iron.
- High tea consumption can inhibit the absorption of iron.
- Folic acid resorption is decreased by ethanol and phenytoin.
- Barbiturates, cycloserine and oral contraceptives cause a drop in blood levels of folic acid.
- Methotrexate, pyrimethamine, trimethoprim and triamterene, which are folic acid antagonists, can cause anaemia.
- Folic acid has an antagonistic action to sulphonamides.
- Some tuberculostatic drugs can influence the action of folic acid.

FERCEFOL® with food and drink

For better absorption, FERCEFOL® should preferably be taken with food.

Pregnancy, breast-feeding 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.
At normal dosage levels, FERCEFOL® is safe to use during pregnancy and breast-feeding.

Driving and using machines

FERCEFOL® has no or negligible influence on the ability to drive and use machines.

Excipients with known effect

- FERCEFOL® coated tablets contain sucrose: if your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.
- FERCEFOL® coated tablets contain chocolate supra (E110, E133, E124), which may cause skin reactions.
- FERCEFOL® syrup contains 500 mg of sorbitol (E420) per 5 ml of syrup, FERCEFOL® oral solution contains 1g of sorbitol (E420) per 10 ml of oral solution; sorbitol content in oral medicinal products can interfere with bioavailability of other concomitant drugs taken orally.
- FERCEFOL® syrup and FERCEFOL® oral solution contain glucose syrup, which may be harmful for teeth.

- FERCEFOL® syrup and FERCEFOL® oral solution contain sodium benzoate (E211) which may increase the risk of jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks of age).
- FERCEFOL® syrup and FERCEFOL® oral solution contain sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217) and ponceau red 4R (E124) which may cause allergic reactions (possibly delayed).

3. HOW TO TAKE FERCEFOL®?

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.
The doctor will determine the dosage depending on the severity of your condition.

Posology

Coated tablet :

Best taken before a meal, depending on digestive tolerance, with a glass of water.

- Iron-deficiency anaemia:
  Adults: 1 tablet, 1 to 2 times a day. Minimum treatment duration 4 to 6 months, in combination with aetiological treatment. Representing 100 to 200 mg of elemental iron equivalent and 4 to 8 mg of folic acid per day.
- Maintenance dose:
  Adults: 1 tablet per day.

Syrup :

The syrup form is more suitable for children.
Best taken before a meal, depending on digestive tolerance, with a glass of water.

- Iron-deficiency anaemia:
  Adults: 1 to 2 doses of 5 ml per dose. 1 to 2 doses per day minimum treatment duration 4 to 6 months, in combination with aetiological treatment. Representing 50 to 200 mg of elemental iron equivalent and 2 to 8 mg of folic acid per day.
  Children and infants: the dose is calculated on the basis of elemental iron dosage: i.e. 6 to 10 mg/kg/day in one or two administrations. Minimum treatment duration 4-6 months, in combination with aetiological treatment.
- Maintenance dose:
  Adults: 1 to 2 doses of 5 ml per day.

Oral solution :

Best taken before a meal, depending on digestive tolerance, with a glass of water.

- Iron-deficiency anaemia:
  Adults: 1 to 3 stick packs of 10 ml per day minimum treatment duration 4-6 months, in combination with aetiological treatment. Representing 100 to 300 mg of elemental iron equivalent and 4 to 12 mg of folic acid per day.
- Maintenance dose:
  Adults: 1 stick pack of 10 ml per day.

Route of administration

Route of administration: oral.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects although not everybody gets them.
During treatment with FERCEFOL®, you may experience one or more of the following side effects at the following frequencies:

Very common (may affect up to 1 in 10 people):

· dark stool colour

Common (may affect up to 1 in 10 people):

· diarrhoea,
· nausea,
· gastrointestinal disorders

Uncommon (may affect up to 1 in 100 people):
· vomiting,
· constipation,
· abdominal pain,
· tooth discolouration,
· skin rash,
· itching,
· headaches.

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. By reporting side effects, you can help provide more information about the safety of this medicine.

5. HOW TO STORE FERCEFOL® ?
Keep this medicine out of sight and reach of children.
Do not use FERCEFOL® after the expiry date, which is stated on the outer packaging. The expiry date refers to the last day of that month.
Store away from heat, light and humidity, at a temperature not exceeding 30°C.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
Swelling of the cells in the strip containing FERCEFOL® coated tablets is sometimes observed, this is due to the airtight nature of the aluminium making up the strips. This does not affect the quality of FERCEFOL® in any way.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What does FERCEFOL® contains?
FERCEFOL® coated tablets:

Ferrous fumarate:	308 mg (equivalent to 100 mg of elemental iron)
Vitamin C:	200 mg
Folic acid:	4 mg

Excipients: maize starch, sucrose, purified talc, magnesium stearate, beeswax, chocolate supra (E155), gelatin, shellac.

FERCEFOL® syrup, each 5 ml contains:

Iron (III)-hydroxide polymaltose:	50 mg (equivalent to 50 mg of elemental iron)
Vitamin C:	100 mg
Folic acid:	2 mg

FERCEFOL® oral solution, each sachet contains:

Iron (III)-hydroxide polymaltose:	100 mg (equivalent to 100 mg of elemental iron)
Vitamin C:	200 mg
Folic acid:	4 mg

Excipients: Liquid glucose, sorbitol, xanthan gum, sodium benzoate (E211), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), sodium edetate, sodium saccharin, raspberry essence, ponceau-4R supra (E124), sodium hydroxide, purified water.

Each 5 ml dose contains 1 g of glucose.
Each 10 ml dose contains 2 g of glucose.

What FERCEFOL® looks like and contents of the pack
FERCEFOL® coated tablets: box with 30 coated tablets in aluminium strips of 10 tablets each.
FERCEFOL® syrup: 150 ml bottle accompanied by a 15 ml measuring cup.

FERCEFOL® oral solution: stick pack of 10ml, box of 20 stick pack.

Not all pack sizes may be marketed.

Marketing authorization holder
Exphar sa
Zoning Industriel de Nivelles Sud, Zone II
Avenue Thomas Edison 105 – 1402 Thines (Belgium)

Manufacturer:
Gracure Pharmaceuticals Ltd.
E-1105 RIICO Industrial Area, Phase III, Bhiwadi, Alwar (Rajasthan) (India)

The last date of the package leaflet was revised is 06/2024.