SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FERLIX® Folix Film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For each tablet:
Ferrous Sulphate B.P .... 200 mg
Ferrous Iron eqv. ....65 mg
Folic Acid Hydrate B.P.
Folic acid eqv. ..... 0.4 mg

Excipient with notorious effect:
Lactose, each tablet contains 1.25 mg Lactose.

For a list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablets

Description: Red, round, biconvex film-coated tablets.

4. CLINICAL DATA

4.1 Therapeutic indications

It is recommended for the treatment of iron deficiency anaemia associated with folate deficiency in adults and children over 12 years of age, and as a preventive treatment for iron deficiency associated with folate deficiency in pregnant women.

4.2. Dosage and mode of administration

Curative treatment:
Adults: 1 tablet, 2 to 3 times daily.
Children over 12 years: 1 to 2 tablets per day.
Duration of treatment according to the doctor's advice.

Preventive treatment:
In pregnant women: 1 tablet per day during the last two trimesters of pregnancy (or from the fourth month).

Duration of treatment: 3 to 6 months according to the doctor's advice.

Duration of treatment:
It should be sufficient, between 3 and 6 months, to correct the anaemia and restore the iron reserves which, in adults, are about 1000 mg.

Method of administration
Oral use.

The tablets should not be sucked, chewed or held in the mouth, but swallowed whole with water.
The tablets should be taken before or with meals, depending on gastrointestinal tolerance. In order to limit the side effects and because of the stimulating effect of vitamin C, it is advisable to take this medicine on an empty stomach in the morning or before breakfast, but the time of intake and possibly the dosage should be adapted according to the digestive tolerance.

4.3. Contraindications

Marginal overload, in particular normo - or hypersidermic anaemia such as thalassaemia, refractory anaemia, anaemia due to bone marrow failure.

Hypersensitivity to folic acid or iron or to any of the excipients.
Iron overload (e.g. haemochromatosis, haemosiderosis).
Patients who have had repeated blood transfusions.
Megaloblastic anaemia due to vitamin B12 deficiency.
Concomitant parenteral iron therapy.

4.4. Special warnings and precautions for use
The product contains lactose and is therefore not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

Special warnings
You should consult your doctor before using this medicine. This medicine should not be used in patients with haemochromatosis or other disorders in which there is excessive absorption and storage of iron. It is not suitable for patients receiving blood transfusions or intravenous iron.

Precautions for use
- The prevention of martial deficiency in infants is based on the early introduction of a diversified diet.
- High tea consumption inhibits the absorption of iron.
- Due to the risk of mouth ulcers and discolouration of the mouth, the tablets should not be sucked, chewed or held in the mouth, but swallowed whole with water.
- Aspiration of iron sulphate tablets into the airways may induce necrosis of the bronchial mucosa which may lead to cough, haemoptysis, bronchial stenosis and/or lung infection (even if the aspiration took place days or months before the onset of these symptoms). Elderly patients and patients with swallowing difficulties should be treated with iron sulphate tablets only after careful assessment of their individual risk of aspiration. The use of other formulations should be considered. Patients should seek medical advice if aspiration is suspected.
- An efficacy check is useful after 3 months of treatment: it should focus on the correction of anaemia (Hb, VGM) and on the restoration of iron stocks (serum iron and siderophilin saturation).

4.5. Interaction with other medicinal products and other forms of interaction

Tetracyclines: Iron sulphate may interfere with the gastrointestinal absorption of tetracyclines and vice versa. Therefore, these drugs should be taken within 2 to 3 hours.

Quinolones: Ferrous sulphate also interferes with the absorption of quinolones (ciprofloxacin, norfloxacin, ofloxacin), resulting in decreased serum and urine concentrations of these antimicrobial agents. Therefore, these drugs should be administered within 2 hours.

Thyroxine: Signs of hypothyroidism may be observed in patients receiving thyroxine (ferrous sulphate and thyroxine form an insoluble complex, resulting in decreased thyroxine absorption).

Penicillamine: Iron also reduces the cupruretic effect of penicillamine, probably by decreasing its absorption. Therefore, 2 hours should elapse between the administration of penicillamine and iron.

Antacids: Concurrent administration of antacids decreases iron absorption.

Chloramphenicol: The response to iron therapy may be delayed in patients receiving chloramphenicol. Co-administration of folic acid and chloramphenicol in folate-deficient patients may antagonise the haematopoietic response to folic acid.

Ascorbic acid: Ascorbic acid increases the absorption of iron.

Phenytoin: In patients with epilepsy who are being treated with phenytoin, drugs containing folic acid may increase the metabolism of phenytoin, reduce its serum levels and increase the frequency of seizures.

Methyldopa: Iron sulphate decreases the absorption and affects the metabolism of methyldopa and may reduce its hypotensive effect.
Many foods and vitamin supplements can reduce the absorption of iron:- tea, coffee, milk, cereals, calcium supplements and medicines containing bicarbonate, carbonate, oxalates or phosphates.

4.6. Fertility, pregnancy and lactation
Pregnancy
The negative clinical data from a few thousand treated women seem to exclude an adverse effect of ferrous sulphate.
Therefore, under normal conditions of use, this medicine may be prescribed during pregnancy**.**

Breastfeeding
The passage of ferrous sulphate into breast milk has not been evaluated, but due to the nature of the molecule, administration to nursing mothers is possible.

4.7. Effects on ability to drive and use machines
Not applicable.

4.8. Undesirable effects
Post-marketing: The following adverse reactions have been reported during post-marketing surveillance. The frequency of these reactions is considered indeterminate (cannot be estimated on the basis of available data).

Gastrointestinal disorders:
Gastrointestinal disturbances such as nausea, constipation or diarrhoea may occur.
The usual colour of the stool is black or grey-black.
- Mouth ulcers*.

In case of incorrect administration, when tablets are chewed, sucked or held in the mouth. Elderly patients and patients with swallowing difficulties may also be susceptible to oesophageal damage or bronchial necrosis if administered incorrectly.
Immune system disorders:

- Allergic reactions such as rash, urticaria and exceptionally anaphylactic shock have been reported.

Respiratory, thoracic and mediastinal disorders:
Bronchial stenosis (see section 4.4).

4.9. Overdose
In case of massive ingestion of iron salts, cases of overdose have been reported, especially in children under 2 years old:
- Symptoms include signs of intense irritation or necrosis of the digestive mucosa leading to abdominal pain, vomiting, often bloody diarrhoea which may be accompanied by shock with acute renal failure, liver damage, and coma which is often convulsive.
- At a distance from the intoxication, digestive stenosis is possible.
- Treatment should be administered as soon as possible by gastric lavage with 1% sodium bicarbonate solution.
- The use of a chelating agent is effective, the most specific being deferoxamine, mainly when the serum iron concentration is above 5 microg/ml. Shock, dehydration and acid-base abnormalities are treated in the conventional way.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Anti-anaemic preparations - Iron in combination with folic acid

ATC Code: B03AD03

Ferlix® Folix Film-coated tablet contains two important micronutrients as active ingredients - iron and folic acid.

Ionic iron is essential for the synthesis of haemoglobin and myoglobin, compounds required for oxygen transport and utilisation. Iron is also a component of a number of enzymes required for energy transfer, for example cytochrome oxidase, xanthine oxidase and succinic dehydrogenase.

Folic acid is a vitamin that is essential for a number of metabolic reactions that are essential to life, such as the synthesis of purines, the synthesis of pirimidine nucleotides, and the interconversion of amino acids (serine to glycine, histidine to glutamic acid, homocysteine to methionine).

Iron and folic acid are essentially two factors that are necessary for the successive phases of haematopoiesis.

5.2. Pharmacokinetic properties

Iron
Iron absorption can occur along the entire length of the gastrointestinal tract, is maximal in the proximal duodenum and jejunum and decreases progressively distally. It is influenced by many factors, including the dose administered, iron stores, the degree of erythropoiesis, the iron in the diet and the form in which it is administered (iron sulphate is the salt with the best bioavailability). About 5-15% of dietary iron is absorbed in healthy people and about 60% in iron-deficient people. However, the absorption of iron is decreased when it is given with many foods or with certain medications.

Iron absorption decreases when iron stores are high. A healthy individual can control gastrointestinal absorption of iron, even when given in high doses, but this is not the case in people with the haemochromatosis genotype.

After oral administration, iron passes through the cells of the gastrointestinal mucosa directly into the blood and is immediately bound to transferrin. Transferrin, a β1-globulin glycoprotein, transports iron to the bone marrow where it is incorporated into haemoglobin during haematopoiesis.

Only a small amount of iron is excreted and most of the iron released by the destruction of haemoglobin is reused by the body.

Folic acid
Folic acid is rapidly absorbed from the gastrointestinal tract after oral administration, mainly in the proximal part of the small intestine. Naturally occurring folate polyglutamates are enzymatically hydrolysed in the gastrointestinal tract to the monoglutamate forms of folic acid before absorption. The mucosa of the duodenum and upper jejunum is rich in dihydrofolate reductase, which is capable of methylating the reduced folate that is absorbed. After oral administration, peak folate activity in the blood occurs within 30-60 minutes.

Tetrahydrofolic acid and its derivatives are distributed throughout the body; the liver contains about half of the body's total folate stores.

Folic acid is a water-soluble B-complex vitamin, whose elimination is mainly renal, and accumulation is not observed. When maximum renal tubular reabsorption is exceeded, after oral administration beyond the daily requirement, folate is excreted unchanged in the urine.

5.3. Preclinical safety data
Unknown

6. PHARMACEUTICAL DATA

6.1. List of excipients
Starch, Purified Talc, Microcrystalline cellulose, Sucrose, Liquid glucose, Lactose, P.V.P.K.-30, Ethyl cellulose, Magnesium stearate, Sodium starch glycolate, Sodium croscarmellose, Sodium lauryl sulphate, Hydroxypropyl methyl cellulose, Red iron oxide (E172), Ponceau Lake 4R (E124), Polyethylene glycol, Titanium dioxide, Triacetin.

6.2 Incompatibilities
Not applicable.

6.3. Shelf life
3 years.

6.4. Special precautions for storage
No special precautions for storage.
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 box after EXP. The expiry date is the last day of the month indicated.
Do not store above 30°C. Protect from moisture and light.

6.5. Nature and contents of the container
10 tablets in blister pack (PVC/Aluminium), 3 blister packs/box.

6.6. Special precautions for disposal and other handling
No special requirements for disposal

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorisation Holder:
B&O PHARM,
ZAC de la Masquère - 500 rue de l'Hers - 31750 ESCALQUENS, France.

Manufacturer:
Bio Nova Pharmaceuticals Pvt. Limited
C-66/1, Okhla Industrial Area, Phase-II, New Delhi - 110020, India.

8. MARKETING AUTHORIZATION NUMBERS
TAN 22 HM 0154

9. DATE OF FIRST AUTHORIZATION
11/04/2022

10. DATE OF REVISION OF THE TEXT