SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

FORIC PREGNANCY Tabs

Ferrous Fumarate, Folic Acid

Tablets

2. Qualitative and quantitative composition

Each tablet contains:
Ferrous Iron (as ferrous fumarate) 100 mg
Folic Acid 400 mcg

3. Pharmaceutical form

Tablets

4. Clinical particulars

4.1 Therapeutic indications

The medicine is intended for the prophylaxis and treatment of iron and folic acid deficiencies in non-pregnant women, pregnant and breast-feeding women and men.

For children above age 12.

4.2 Posology and method of administration

Prophylaxis of Anaemia: 1 tablet per day

Treatment for Anaemia: 1-3 tablets per day.

Pregnancy: One tablet daily throughout pregnancy or as directed by a physician.

It is usual to begin therapy about the thirteenth week of pregnancy either as routine prophylaxis or selectively if the haemoglobin concentration is less than 11g/100ml (less than 75% normal).

The Tablets are indicated during the second and third trimester of pregnancy for prophylaxis against iron deficiency and megaloblastic anaemia of pregnancy.

There is evidence that a daily intake of 100mg of elemental iron in the ferrous form is adequate to prevent development of iron deficiency in expectant mothers.

Method of administration:

For oral administration.

To be taken with water 2-3 hours after a meal or one hour before.

In case of digestive side effects, the dose should be taken with or after food.

If required, the tablets can be crushed and swallowed immediately.

In case of a forgotten dose, no need for a double dose.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

The medicine should not be used:

- In the presence of megablastic anaemia due to primary vitamin B12 deficiency or any undiagnosed anaemia.
- In patients with anaemias other than those due to iron deficiency and patients with high iron levels.
- In patients with inflammatory bowel disease, including regional enteritis and ulcerative colitis, intestinal diverticular or any intestinal obstruction, active peptic ulcer.
- In patients with haemosiderosis, haemochromatosis and haemoglobinopathies.
- In patients who require repeated blood transfusion.
- With concomitant use of parenteral iron or other iron products.
- Kown iron metabolism disorder in the body.
- During the first 13 weeks of pregnancy only in consultation with a doctor.

4.4 Special warnings and precautions for use

During the first 13 weeks of pregnancy, only in consultation with a doctor.

Consult with the doctor in case of disorders in:

- Gastro-intestinal system (e.g., ulcer, intestinal inflammation), liver, kidnyeis /urinary system,
- Vascular system (e.g., erythropoietic protoporphyria, malignant anaemia),
- repeated blood transfusions,
- Infections,
- Diabetes,
- Some post-gastrectomy patients show poor absorption of iron,
- Caution should be exercised when administering folic acid to patients who may have folate dependent tumors,
- Folic acid may prevent detecting vitamin B12 deficiency,
- Caution is advised in individuals with a family history of haemochromatosis or iron overload syndromes. It should be noted these conditions may be under diagnosed.

- As with all iron preparations, this product should be used with caution in patients with haemochromatosis, haemolytic anaemia or haemoglobinopathies.
- Since anaemia due to combined iron and vitamin B12 or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to therapy with iron alone should be screened for vitamin B12 or folate deficiency.
- Iron preparations colour the faces black, which may interfere with tests used for detection of occult blood in the stools.

  Blood tests are required during treatment.

4.5 Interaction with other medicinal products and other forms of interaction

- Iron preparations, parenteral iron.

- Iron salts diminish the absorption of tetracyclines, Tetracycline antibiotics should be taken at least 2 hours before or 4 hours after taking the medicine.
- Follow up is required when antibiotics are used: Concurrent administration of oral iron preparations may interfere with the oral absorption of some quinolone anti-infective agents (e.g., ciprofloxacin, norfloxacin, ofloxacin), resulting in decreased serum and urine concentrations of the quinolones, Therefore, oral iron preparations should not be ingested within one hour before or within four hours of a dose of an oral quinolone. As well as for penicillin, chloramphenicol.
- Thyroid hormones: Oral iron reduces the absorption of levothyroxine (thyroxine) thus should be given at least 2 hours apart.
- Iron salts may reduce the bioavailability of Vitamin B12, zinc, methyldopa, the absorption of levodopa and penicillamine may also be reduced.
- The absorption of iron salts is decreased in the presence of antacids and preparations containing calcium, phosphorus or when taken with tea, coffee, milk, eggs, wholegrain cereals and dietary fiber, alcohol. Therefore, oral iron preparations should not be taken within at least two hours after ingestion of these products.
- Iron absorption may be increased by ascorbic or citric acid.
- Serum levels of anticonvulsant drugs may be reduced by the co-administration of folate, the medicine may possibly reduce the plasma concentration of phenobarbital, phenytoin and primidone.
- Absorption is possibly reduced also by sulfasalazine.
- Anti cancer medication (aminopyrine, methotrexate)
- Pyrimethamine for malaria
- Triantine for Willson disease
- Cholestyramine
- Excessive alcohol consumption can influence vitamin absorption.

4.6 Pregnancy and lactation

The medicine is indicated for the prophylaxis of iron and folic acid deficiencies.
It should only be taken during the first 13 weeks of pregnancy in consultation with a doctor.
However, administration of drugs during the first trimester of pregnancy requires careful assessment of potential risks versus benefits to be gained.
Iron is excreted in breast milk so consult your doctor if you intend breast feeding.

4.7 Effects on ability to drive and use machines

The medicine has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Side effects that require stopping the treatment and referring to the doctor as soon as possible:
Severy stomach pain, vomiting, allergic reaction-swelling of face, lips, eyelids, skin rash with irritation, itching, breathing difficulties, fainting

Very common (more than 10%):
Iron preparations color the faces black, there is no clinical significance.
nausea, abdominal pain or discomfort, digestive difficulties, blackening of stools, diarrhoea and/or constipation,

Rare (up to 1%)
Vomiting, vomiting with blood, constipation, teeth color change, headache.

Additional side effects:
Pressure in the upper part of the stomach, intestinal obstruction, feeling full
Haematemesis and ileus have been reported.
Immune system disorders: Anaphylactic reaction.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

4.9 Overdose

In case of suspected overdose, the patient should refer immediately to the hospital or emergency room with the medicine's package.
Initial symptoms of iron overdosage include nausea, vomiting, abdominal pain, diarrhoea, haematemesis and rectal bleeding.
If overdosage is suspected treatment should not be delayed.

A latent phase followed by a relapse 24 – 48 hours after ingestion manifest by hypotension, coma and hepatocellular necrosis may occur.

Overdose may be fatal especially in children.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Iron aids haemoglobin regeneration. Once haemoglobin returns to normal, continuing with iron supplementation for three months will help replenish the iron stores within the body.

5.2 Pharmacokinetic properties

Oral iron is absorbed better when administered between meals; however, conventional iron preparations often cause gastric irritation when taken on an empty stomach.

After absorption, folic acid is rapidly converted into its metabolically active forms. Approximately 2/3 is bound to plasma protein. Half of the folic acid stored in the body is found in the liver. Folic acid is also concentrated in the spinal fluid.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to information contained in this leaflet.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose, Ascorbic Acid, Povidone, Microcrystalline Cellulose, Sodium Starch Glycolate, Magnesium Stearate, Sodium Bicarbonate, Opadry OY-29020, Talc, Titanium Dioxide, Red Lake No 3.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool place, protect from light.

6.5 Nature and contents of container

Pink tablets in blister pack

6.6 Special precautions for disposal.

Not to be discarded at domestic bin and sewage

7. Marketing authorisation holder

Sam-On Ltd.

25 Ehud Kinnamon (haavoda) St.

Bat-Yam 59602

8. Marketing authorisation number(s)

1253430478

9. Date of first authorisation/renewal of the authorisation

2/2002

10. Date of revision of the text

4/2024