FERGOLE

Tablets

Composition

Each coated tablet contains:

Elemental iron (as ferrous fumarate)	106 mg
Folic acid	1 mg

Action

Fergole is a well-balanced, haematinic, preparation containing ferrous fumarate, and folic acid, specifically designed for prophylaxis and treatment of iron and foliate deficiency in pregnancy.

Ferrous fumarate is one of the best-tolerated iron salts, and has high elemental iron content. Folic acid is present to meet the increased requirement for this vitamin during pregnancy, particularly in the last trimester, thus preventing megaloblastic anemia caused by foliate deficiency.

Indications

Prevention of anemia caused by iron and folic acid deficiency, especially that associated with pregnancy.

Contraindications

- Hypersensitivity to any of the components of this preparation.
- Idiosyncrasy to iron preparations. Hemochromatosis, hemosiderosis, hemolytic anemia.

Warnings

Patients with untreated pernicious anemia may show hematological improvement with daily therapeutic doses of folic acid as low as 0.25 mg/day. In such cases, degenerative lesions of the spinal cord may progress irreversibly after 3 months, despite the absence of anemia. Pernicious anemia should be ruled out prior to treatment with this drug.

Resistance to treatment may be due to depressed haematopoiesis, alcoholism, the presence of antimetabolic drugs, and vitamin B6, B12, C or E deficiencies. Iron deficiency anemia may be due to occult blood loss. The cause should be determined and treated appropriately. Iron preparations should be stored out of the reach of children, to protect against accidental iron poisoning.

Adverse Reactions

Oral iron medication, in therapeutic doses, may occasionally cause gastric irritation and abdominal pain with nausea, vomiting, diarrhea or constipation.

Precautions

Particular caution must be exercised when administering iron-containing preparations to patients with peptic ulcer, enteritis or ulcerative colitis. If symptoms of intolerance appear, use of the preparation should be discontinued. Iron preparations impart a black color to stools, and may mask occult blood.

Should gastrointestinal irritation occur, it is recommended that the preparation be taken after meals.

Drug Interactions

Iron/ Oral Tetracyclines

Oral iron preparations interfere with the absorption of oral tetracyclines by forming complexes. At least 2 hours should be allowed between the administrations of the two drugs.

Iron/ Antacids

Antacids taken concurrently with iron preparations decrease iron absorption, administration of the two drugs should be spaced as far apart as possible.

Iron/ Vitamin C

Concurrent treatment with Vitamin C (in excess of 400 mg) is not recommended, as elemental iron absorption in the gastrointestinal tract is increased.

Iron/ Foods

Iron absorption is inhibited by the concurrent ingestion of eggs, milk, tea or coffee.

Folic Acid/ Phenytoin

Concurrent administration has been reported to cause a reduction in both serum foliate and phenytoin concentration (to sub-therapeutic levels). In particular, this has been noted at folic acid doses of 15-20 mg/day.

Folic Acid/ Primidone/ p-Aminosalicylic Acid/ Sulfasalazine.

These drugs may cause a reduction in serum foliate levels, and may produce symptoms of folic acid deficiency during long-term therapy.

Folic Acid/ Pyrimethamine

Folic acid may interfere with the antimicrobial actions of pyrimethamine against toxoplasmosis.

Folic Acid/ Pyrimethamine/ Trimethoprim/ Triamterene

A dihydrofoliate reductase deficiency caused by the administration of these folic acid antagonists may interfere with folic acid utilization.

Diagnostic Interference

Methotrexate, pyrimethamine and most antibiotics invalidate folic acid diagnostic microbiological blood assays.

Dosage and Administration

Initial Dosage

One tablet, twice daily

Maintenance Dosage

One tablet daily

Over Dosage

Iron over dosage is dangerous, particularly in children, and requires immediate attention. Serious poisoning may result in young children following ingestion of as little as 200 mg of elemental iron.

Manifestations

Symptoms of iron over dosage usually occur within about 30 minutes of ingestion, or may be delayed by several hours.

They include signs of abdominal pain, vomiting and diarrhea (appearing within 60 minutes), gastrointestinal irritation and necrosis, tarry stools, hematemesis, fast and weak pulse, lethargy, low blood pressure, coma and signs of peripheral circulatory collapse. Metabolic acidosis, convulsions, fever, leukocytosis, coma and even death may occur 12-24 hours post-ingestion.

Acute hepatic and renal necrosis may follow, 2-4 days post-ingestion. Possible intestinal scarring and obstruction may occur, 2-4 weeks post-ingestion.

Treatment

Administer an emetic such as syrup of ipecac. Emesis should be followed by gastric lavage with desferrioxamine solution (2 grams/litre). Thereafter, instil a more concentrated solution of desferrioxamine (5 grams in 50-100 ml of water), to be retained in the stomach.

Keep the patient under constant surveillance to detect possible aspiration of vomitus. Maintain suction apparatus and standby emergency oxygen in case of need. Following these initial measures, parenteral desferrioxamine treatment should be instituted, taking into account the severity of the poisoning, in accordance with the dosage recommendations set out below.

The patient must be monitored for a minimum of 24 hours after becoming asymptomatic. Delayed effects may include shock, severe gastrointestinal bleeding (24-48 hours), and gastrointestinal obstruction (weeks to months).

Severe Poisoning

In cases of severe poisoning, manifested as shock and/or coma with high serum iron levels (i.e. > 90 μM/litre in children and >142 μM/litre in adults), immediate supportive measures including intravenous infusion of desferrioxamine should be instituted. Note that hypotension may occur if the infusion rate is too rapid.

The recommended dose of desferrioxamine in children is 15 mg/kg body weight/hour by slow I.V. infusion, to a maximum of 80 mg/kg per 24 hours.
The recommended dose in adults of desferrioxamine is 5 mg/kg body weight/hour by slow I.V. infusion to a maximum of 80 mg/kg per 24 hours.

Less Severe Poisoning

The recommended dose in children is 1 gm of desferrioxamine, administered I.M. every 4-6 hours.
The recommended dose in adults is 50 mg/kg body weight of desferrioxamine, administered I.M. up to a maximum dose of 4 grams.

Presentation: Box of 30 tablets.