

FERROLET

Suspension

Composition

Ferrolet 15 Suspension

Each teaspoonful (5 ml) contains:

Iron (as ferrous carbonate)	15 mg
Vitamin C (as sodium ascorbate)	100 mg

Ferrolet 50 Suspension

Each teaspoonful (5 ml) contains:

Iron (as ferrous carbonate)	50 mg
Vitamin C (as sodium ascorbate)	100 mg

Action

Ferrolet contains ferrous carbonate, a well tolerated source of iron for the treatment of iron-deficiency anemias. Ferrous carbonate is as effective as ferrous sulfate, whilst offering the advantage of being palatable and associated with a significantly lower incidence of side effects.

Indications

Ferrolet 15

Prophylaxis and treatment of anemias in infants due to iron deficiency.

Ferrolet 50

Treatment of anemias due to iron deficiency.

Contraindications

- Idiosyncrasy to iron preparations. Hemochromatosis, hemosiderosis, hemolytic anemia.
- Patients with peptic ulcer, regional enteritis or ulcerative colitis.

Warnings

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.

Liquid iron-containing preparations may cause temporary staining of the teeth (or the membrane covering the teeth in infants). To reduce this possibility, the liquid should be diluted or, preferably, be drunk through a straw.

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/ Foods

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

Dosage and Administration

Ferrolet 15

For prophylaxis, the dosage is 1 mg iron/kg daily, to be taken between meals. In babies up to 1 year of age, the minimum dosage is 7.5 mg iron/day and the maximum dosage is 15 mg iron/day.

In the treatment of cases of iron deficiency, the dosage may be increased up to 2 mg iron/kg, 3 times daily.

Ferrolet 50

In adults and children over 6 years of age, 100-150 mg iron/day, in divided doses, to be taken between meals.

In children under 6 years of age, 50-100 mg iron/day, in divided doses, to be taken between meals.

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

Ferrolet 15

Bottle of 100 ml.

Ferrolet 50

Bottle of 100 ml.