

Acufer

Iron (as Ferric Maltol INN)

COMPOSITION

Acufer Capsule: Each capsule contains Ferric Maltol INN equivalent to Iron 30 mg.

PHARMACOLOGY

Acufer delivers iron for uptake across the intestinal wall and transfer to transferrin and ferritin.

INDICATIONS

Acufer is an iron replacement product indicated for the treatment of iron deficiency in adults.

DOSAGE AND ADMINISTRATION

The recommended dosage of Acufer is 30 mg twice daily orally. It should be taken with half a glass of water on an empty stomach. It can be taken 1 hour before or 2 hours after a meal. Do not open, break, or chew Acufer capsules. Treatment duration will depend on the severity of iron deficiency but generally at least 12 weeks of treatment is required. The treatment should be continued as long as necessary until ferritin levels are within the normal range. Or as directed by the physician.

CONTRAINDICATIONS

Acufer is contraindicated in patients with a history of:

- Hypersensitivity to the active substance or to any of the excipients.
- Hemochromatosis and other iron overload syndromes use may result in iron overdose.
- Receiving repeated blood transfusions use may result in iron overload.

WARNING AND PRECAUTION

Increased risk of inflammatory bowel disease (IBD) flare, iron overload, risk of overdosage in children due to accidental ingestion.

SIDE EFFECTS

Common side effects: Flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting and abdominal discomfort/distension. **Rare side effects:** Headache, small intestinal bacterial overgrowth, acne, erythema etc.

USE IN PREGNANCY AND LACTATION

Pregnancy: Acufer is not absorbed systemically as an intact complex following oral administration and maternal use is not expected to result in fetal exposure to the drug. **Lactation:** There are no data on the presence of Acufer in human milk, the effects on the breastfed child or the effects on milk production.

USE IN CHILDREN & ADOLESCENTS

Safety and effectiveness of Acufer in children & adolescents (17 years & under) has not yet been established.

DRUG INTERACTIONS

With medicine: Avoid concomitant use of Acufer with dimercaprol. **With food & others:** Food has been shown to decrease the bioavailability of iron.

OVERDOSE

No data is available regarding overdose of Acufer in patients. Acute iron ingestion of 20 mg/kg elemental iron is potentially toxic and 200- 250 mg/kg is potentially fatal.

STORAGE

- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

PACKING

Each box contains 60 capsules in alu-alu blister pack.