# FERRITIN® OTI

Children "40 mg/8 ml syrup", 10 single dose vials
Adults "62.5 mg/8 ml syrup", 10 single dosevials
"62.5 mg/8 ml syrup", 240 ml bottle
"62.5 mg hard capsules, 20 capsules
ATC: B03AB49 Sodium ferric gluconate complex

**COMPOSITION**

**- Children "40 mg/8 ml syrup", 10 single dose vials**

Each vial contains:
Active principle: Sodium ferric gluconate complex 113.6 mg
(equivalent to 40 mg Fe++)
Excipients: saccharose, glycerin, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, ethyl p-hydroxybenzoate, dehydroacetic acid sodium salt, Dutch cream flavour, purified water q.s.

**- Adults "62.5 mg/8 ml syrup", 10 single dose vials**

Active principle: Sodium ferric gluconate complex 177.5 mg
(equivalent to 62.5 mg Fe++)
Excipients: saccharose, glycerin, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, ethyl p-hydroxybenzoate, dehydroacetic acid sodium salt, Dutch cream flavour, purified water q.s.

**- "62.5 mg/8 ml syrup", 240 ml bottle**

100 ml of syrup contain:
Active principle: Sodium ferric gluconate complex 2218.7 mg
(equivalent to 781.2 mg Fe++)
Excipients: saccharose, glycerin, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, ethyl p-hydroxybenzoate, dehydroacetic acid sodium salt, Dutch cream flavour, purified water q.s.

**- "62.5 mg hard capsules", 20 capsules**

Each capsule contains:
Active principle: Sodium ferric gluconate complex 177.5 mg
(equivalent to 62.5 mg Fe++)
Excipients: talc, magnesium stearate, colloidal silica, corn starch, levilite, titanium dioxide, gelatin.

**PHARMACEUTICAL FORM, PACKAGE**

- Children 40 mg/8 ml syrup: 10 vial box
- Adults 62.5 mg/8 ml syrup: 10 vial box
- 62.5 mg/8 ml syrup: 240 ml bottle
- 62.5 mg hard capsules: 20 capsule box

**PHARMACOTHERAPEUTIC CATEGORYA**

Antianemic, oral preparations. Trivalent iron.

**MARKETING AUTHORISATION HOLDER**

ABC FARMACEUTICI SpA - Corso Vittorio Emanuele II, 72 - 10121 TURIN, ITALY

**- Vials and Syrupl**

A. ABC FARMACEUTICI S.p.A
Strada Vicinale dei Moretti 1- Ivrea (Turin)
B. ISTITUTO BIOLOGICO CHEMIOTERAPICO S.p.A.
Via Silvio Pellico 3 – Trecate- NO (only controls)

**THERAPEUTIC INDICATION**

Iron deficiency conditions. Essential hypochromic anaemia.
Chloranaemia, haemorrhage-related anaemia, iron-deficiency anaemia, oligaemic syndromes of toxic-infective and deficiency origin in infancy and puberty, gravidic anaemia.
As an adjuvant during convalescence and growth.

**CONTRAINDICATIONS**
Known hypersensitivity against any of the components. Haemochromatosis, haemosiderosis, haemolytic anaemia.

**PRECAUTIONS**
No special precautions are required.
FERRITIN OTI syrup has a child-proof cap. To open the bottle, press the cap downwards and turn it anticlockwise at the same time.

**INTERACTIONS**
Iron and its derivatives may reduce tetracycline absorption.

**WARNINGS**
FERRITIN OTI does not affect the capacity of driving vehicles or operating machines.
FERRITIN OTI for paediatric patients, and FERRITIN OTI vials and syrup contain 37.5 mg of saccharose in 100 ml. If taken at the recommended dose, each dose supplies 3 g of saccharose. FERRITIN OTI for paediatric patients, and FERRITIN OTI vials and syrup, for their saccharose content are contraindicated in cases of hereditary fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase deficiency.

KEEP OUT OF REACH OF CHILDREN.

**DOSAGE AND ADMINISTRATION**

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|---|---|
| **- Bb 40 mg/8 ml syrup:** | one vial, twice daily with meals |
| **- Ad 62.5 mg/8 ml syrup:** | Adults: one vial, twice daily with meals<br>Children: half the adult dose |
| **- 62.5 mg/8 ml syrup:** | Adults: one 8 ml measuring cup twice daily, with meals<br>Children: half the adult dose |
| **- 62.5 mg:** | Rigid capsules - one capsule twice daily, with meals<br>Children: half the adult dose |

**OVERDOSE**
In case of overdose transient intestinal side effects may occur, which should be treated symptomatically, if necessary.

**ADVERSE REACTIONS**
Like all iron-based preparations, excessive oral doses may cause adverse gastrointestinal reactions (diarrhoea, pyrosis, nausea, vomiting). Prolonged administration of the preparation may cause constipation. The faeces may become darker; this, however, has no pathological significance.
Any adverse reactions not described in this leaflet should be immediately notified to the treating physician or to the pharmacist.

**CAUTION:** check the expiry date printed on the package. Do not use after the date indicated with exp. on the package.

**Approved by the Ministry of Health in March 2003**