



# FERPLEX 40 mg/15 ml Oral Solution

B03AB09 IRON PROTEINSUCCINYLATE

## COMPOSITION

One vial 15 ml contains: Iron Proteinsuccinylate mg 800 (equivalent to 40 mg of  $\text{Fe}^{2+}$ ) *Excipients:* Sorbitol E420, propylene glycol, methyl-p-hydroxybenzoate sodium salt, propyl-p-hydroxybenzoate sodium salt, Morella flavour, sodium saccharin, purified water

## PHARMACEUTICAL FORM AND CONTENTS

Oral Solution.

FERPLEX 40 mg/15 ml Oral Solution – 10 vials (single dose container) 15 ml.

## PHARMACOTHERAPEUTIC CLASSIFICATION

Antianemic drug containing trivalent iron, for the treatment of iron deficiency anemia.

## INDICATIONS

Treatment of iron deficiency and iron deficiency anemia: latent or overt iron deficiency anemia in children and adults, secondary to chronic blood loss, pregnancy; breast-feeding.

## CONTRA-INDICATIONS

Hypersensitivity to the active substance or to any of the excipients. Haemosiderosis, haemochromatosis. Aplastic and haemolytic anemias, anemias due to disturbances of iron utilization (sideroachrestic anemias). Chronic pancreatitis and liver cirrhosis secondary to haemochromatosis.

## PRECAUTIONS FOR USE

No particular warnings are required about risks of tolerance or addiction. The treatment should not exceed 6 months, unless in case of persisting bleeding, menorrhagia or pregnancy.

## INTERACTIONS

Iron may impair absorption or bioavailability of: tetracyclines, biphosphonates, quinolone antineoplastic agents, penicillamine, thyroxine, levodopa, carbidopa, alpha-methyldopa. FERPLEX should be given with 2 hours interval from administration of any of these drugs.

Iron absorption may be increased by the concomitant administration of over 200 mg of ascorbic acid or reduced by the concomitant use of antacids. Chloramphenicol may delay response to iron treatment.

No pharmacological interaction was reported during concomitant treatment with  $\text{H}_2$ -antagonists.

Iron complexing agents (such as phosphates, phytates and oxalates) contained in vegetables and in milk, coffee and tea inhibit the absorption of iron. FERPLEX should be given with 2 hours interval from intake of such foods and beverages.

## SPECIAL WARNINGS

Any disease possibly underlying iron deficiency or iron deficiency anemia must be ascertained and properly treated.

As the product contains milk proteins, it must be used with caution in patients suffering from milk-protein intolerance, who may have allergic reactions.

FERPLEX vials contain sorbitol, therefore patients with rare hereditary fructose intolerance must not take this medicine. FERPLEX vials contain parabens (methyl-p-hydroxybenzoate sodium salt, propyl-p-hydroxybenzoate sodium salt) that may cause delayed allergic reactions.

## DOSAGE AND METHOD OF ADMINISTRATION

*Adults:* 1 to 2 vials a day (equivalent to 40–80 mg of  $\text{Fe}^{2+}$ ), as directed by the doctor, in two administrations, preferably before food.

*Children:* Take 1.5 mL/kg/die from a vial (equivalent to 4 mg/kg/die of  $\text{Fe}^{2+}$ ), or as directed by the doctor, in two administrations, preferably before food.

Drink the solution out of the vial or dilute it in natural water.

**Duration of treatment:** the treatment must be carried on until total recovery of normal iron stores (usually for two-three months).

**Maximum daily dose:** clinical trials on the product effectiveness and tolerability were made administering the product at the above specified dosage levels (adults: 1600 mg/day – Children: 1.5 of mL/kg/day of iron proteinsuccinylate); no data about clinical efficacy and tolerability of higher dosages of the product are available.

## OVERDOSAGE

Following ingestion of high doses of ferrous salts, epigastric pain, nausea, vomiting, diarrhoea, and haematemesis, often associated with drowsiness, paleness, cyanosis, shock up to coma may occur. Treatment is immediate administration of an emetic, if necessary followed by gastric lavage, associated with suitable supportive measures. If necessary, iron-chelating agent, such as desferrioxamine, may be administered.

## UNDESIRABLE EFFECTS

Very rarely gastrointestinal disorders such as diarrhoea, stipsis, nausea, epigastric pain may occur; these adverse reactions can be abated by dose reduction or treatment withdrawal. Iron products may turn the colour of stools into black or dark grey.

*Undesirable effects can be avoided by strictly following the instructions of this leaflet.*

*Inform your doctor or pharmacist of any undesirable effects, even if not described in this leaflet.*

## EXPIRY AND STORAGE

**Expiry:** See the date marked on the carton, provided the package is undamaged and correctly stored.

**Storage:** This medicinal product does not require any special storage conditions.

**CAUTION:** do not use the medicine after the expiry date marked on the carton.

**Keep out of the reach of children.**

**Manufactured by :**

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