# SMPC FOR JESSY FERROUS SULPHATE TABLET

## 1. Name of the medicinal product

Jessy Ferrous Sulphate Tablets

## 2. Qualitative and quantitative composition

Ferrous Sulphate 200mg equivalent to 64mg of ferrous iron, Fe(II).

For a full list of excipients, see section 6.1

## 3. Pharmaceutical form

Tablet

Red, sugar-coated tablets.

## 4. Clinical particulars

### 4.1 Therapeutic indications

Ferrous Sulphate is used for iron-deficiency anaemia.

### 4.2 Posology and method of administration

For iron-deficiency anaemia:-

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|---|---|
| **Adults:-** | Prophylaxis - One tablet daily |
| | Therapeutic - One tablet 2-3 times daily |
| **Elderly:-** | As for adults |
| **Children:-** | This presentation is not recommended. |

**Method of administration:**

The tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

Tablets should be taken before meals or during meals, depending on gastrointestinal tolerance.

### 4.3 Contraindications

Hypersensitivity to the product and its ingredients; haemosiderosis and haemochromatosis; active peptic ulcer; repeated blood transfusion; haemolytic anaemia. Oral and parenteral iron preparations should not be used concomitantly.

Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrase- isomaltase insufficiency should not take this medicine.

### 4.4 Special warnings and precautions for use

Patients post-gastrectomy have poor absorption of iron. Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer, and inflammatory bowel disease, including regional enteritis and ulcerative colitis. Care should be taken in patients with intestinal strictures or diverticulae. Duration of treatment should generally not exceed 3 months after correction of anaemia. Co-existing deficiency of vitamin $B_{12}$ or folic acid should be ruled out since combined deficiency produces microcytic blood film. Dental caries is a definite risk following long term treatment with this product. These tablets contain sugar and should be administered with care to patients with diabetes. Patients suffering from iron overload are particularly susceptible to infection. Treatment of iron overload should be with caution.

Due to the risk of mouth ulcerations and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

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The label will state:

"Important warning: Contains iron. Keep out of the sight and reach of children, as overdose may be fatal."

**4.5 Interaction with other medicinal products and other forms of interaction**

Antacids and mineral supplements: Compounds containing calcium, magnesium (including antacids and mineral supplements), bicarbonates, carbonates, oxalates or phosphates may impair the absorption of iron. Administration of iron preparations with such compounds should be separated by at least 2 hours.

**Antibacterials:** Iron and tetracyclines reduce the absorption of each other when administered concomitantly. Administration of iron preparations and tetracyclines should be separated by 2 to 3 hours. Iron may reduce the absorption of quinolones. Administration of iron preparations and quinolones should be separated by at least 2 hours. Chloramphenicol delays plasma clearance of iron, incorporation into red blood cells by interfering with erythropoiesis.

**Biphosphonates:** The absorption of biphosphonates is reduced when taken concurrently with iron preparations. Administration should be separated by at least 2 hours.

**Cholestyramine:** Absorption of iron is impaired by cholestyramine.

Dimercaprol: Concomitant administration of oral iron preparations and dimercaprol should be avoided.

**Dopaminergics:** Oral iron preparations may reduce the absorption of dopaminergics such as co-careldopa, entacapone and levodopa.

**Food Products:** Absorption of iron is impaired by tea, eggs or milk.

**Methyldopa:** Oral iron preparations may antagonise the antihypertensive effect of methyldopa.

Mycophenolate mofetil: Oral iron preparations significantly reduce the absorption of mycophenolate mofetil.

**Penicillamine:** Oral iron preparations can reduce the absorption of penicillamine. Also, the absorption of iron is impaired by penicillamine.

**Thyroid hormone:** Ferrous sulphate reduces the absorption of levothyroxine and so should be taken at least 2 hours apart.

**Trientine:** the absorption of oral iron preparations is reduced by trientine. Administration should be separated by at least 2 hours.

**Zinc:** iron preparations and zinc preparations can reduce the absorption of each other.

**4.6 Pregnancy and lactation**

Use of any drug during the first trimester of pregnancy should be avoided if possible. Thus, administration of iron during the first trimester requires definite evidence of iron deficiency.

Prophylaxis of iron deficiency during the remainder of pregnancy is justified.

**4.7 Effects on ability to drive and use machines**

None known.

**4.8 Undesirable effects**

**Gastro-intestinal disorders:** abdominal pain, nausea and vomiting (these are usually dose related), constipation, diarrhoea and dark stools. Contact irritation can occur with ferrous sulphate

tablets resulting in erosion or ulceration, particularly if they become lodged in the upper gastrointestinal tract.

Allergic reactions have been reported.

**Post-marketing:** The following ADRs have been reported during post-marketing surveillance. The frequency of these reactions is considered not known (cannot be estimated from the available data).

Gastrointestinal disorders:

**mouth ulceration***

* in the context of incorrect administration, when the tablets are chewed, sucked or kept in mouth. Elderly patients and patients with deglutition disorders may also be at risk of oesophageal lesions or of bronchial necrosis, in case of false route.

### 4.9 Overdose

Acute iron overdosage can be divided into four stages. In the first phase, which occurs up to 6 hours after oral ingestion, gastrointestinal toxicity, notably vomiting and diarrhoea, predominates. Other effects may include cardiovascular disorders such as hypotension and tachycardia, metabolic changes including acidosis and hyperglycaemia, and CNS depression ranging from lethargy to coma. Patients with only mild to moderate poisoning do not generally pass this first phase. The second phase may occur at 6-24 hours after ingestion and is characterised by a temporary remission or clinical stabilisation. In the third phase gastrointestinal toxicity recurs together with shock, metabolic acidosis, convulsions, coma, hepatic necrosis and jaundice, hypoglycaemia, coagulation disorders, oliguria or renal failure, and pulmonary oedema. The fourth phase may occur several weeks after ingestion and is characterised by gastrointestinal obstruction and possibly late hepatic damage.

Overdosage of ferrous salts is particularly dangerous to young children.

Treatment consists of gastric lavage followed by the introduction of 5g desferrioxamine into the stomach. Serum iron levels should be monitored and in severe cases iv desferrioxamine should be given together with supportive and symptomatic measures as required. Gastric lavage with 5% sodium bicarbonate and saline cathartics (e.g. sodium sulphate 30g for adults); milk and eggs with 5g bismuth carbonate every hour as demulcents. Blood or plasma transfusion for shock, oxygen for respiratory embarrassment. Chelating agents (e.g. disodium calcium edetate) may be tried (500mg/500ml by continuous iv infusion). Dimercaprol should not be used since it forms a toxic complex with iron. Desferrioxamine is a specific iron chelating agent and severe acute poisoning in infants should always be treated with desferrioxamine at a dose of 90mg/kg im followed by 15mg/kg per hour iv until the serum iron is within the plasma binding capacity.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Ferrous Sulphate contains iron. Most of the iron in the body is present as haemoglobin. The remainder is present in the storage forms ferritin or haemosiderin, in the reticuloendothelial system or as myoglobin with smaller amounts occurring in haem-containing enzymes or in plasma bound to transferrin.

### 5.2 Pharmacokinetic properties

Iron is absorbed mainly in the small intestine, but can be absorbed along the entire length of the alimentary canal. It is absorbed most easily in the ferrous state, passing into and through the mucosal cells directly into the blood stream where it is immediately attached to transferrin.

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**5.3 Preclinical safety data**
None available.

## 6. Pharmaceutical particulars

**6.1 List of excipients**
Light Kaolin

Calcium Carbonate

Magnesium stearate

Corn Starch

Aerosil 200

Granulated Sugar

Gelatin

Methyl Paraben

Propyl Paraben

Gum acacia

Polysorbate 80

**6.2 Incompatibilities**
None relevant known.

**6.3 Shelf life**
Plastic Jars: Three years

**6.4 Special precautions for storage**
Do not store above 30°C

**Plastic Jars :** Store in original container in order to protect from moisture.

**6.5 Nature and contents of container**
Packs of 1000 contained in Plastic Jars

**6.6 Special precautions for disposal and other handling**
Not applicable.

## 7. Marketing authorisation holder

Jessy Pharmaceutical company Limited

## 8. Marketing authorisation number(s)

A11-1304

## 9. Date of first authorisation/renewal of the authorisation

29/09/2022

## 10. Date of revision of the text

28/09/2027