1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

Ferrimed® Capsules

Ferrimed® Syrup

COMPOSITION

Ferrimed® Capsules:

Each capsule contains 50 mg elemental iron as iron (III)-hydroxide polymaltose complex and 150 µg folic acid.

Sugar-free

Ferrimed® Syrup:

Each 5 ml contains 50 mg elemental iron as iron (III)-hydroxide polymaltose complex.

Preservatives:

methylhydroxybenzoate 0,0583 % m/v

propylhydroxybenzoate 0,0167 % m/v

Contains sugar

PHARMACOLOGICAL CLASSIFICATION

A 8.3 Erythropoietics (haematinics)

PHARMACOLOGICAL ACTION

Iron is an essential constituent of the body and is necessary for haemoglobin formation and for the oxidative processes of living tissue.

Pharmacodynamic properties

Ferrimed® contains an iron polymaltose complex consisting of a polynuclear iron (III)-hydroxide core, which is surrounded by a number of non-covalently bound polymaltose molecules.

The absorbed iron is stored mainly in the liver, where it is bound to ferritin. Later in the bone marrow it is incorporated into haemoglobin.

Pharmacokinetic properties

Absorption occurs principally in the duodenum and proximal jejenum.

INDICATIONS

Iron (III)-hydroxide polymaltose complex in the **Ferrimed®** range is indicated for the treatment of iron deficiency and iron deficiency anaemia.

CONTRAINDICATIONS

Cases of iron overload (haemochromatosis; haemosiderosis; chronic haemolysis or lead induced anaemia).

Disturbances in iron utilisation (thalassaemia or sideroblastic anaemia).

Patients showing hypersensitivity and intolerance to iron.

Patients receiving repeated blood transfusions.

All forms of anaemia without iron deficiency, e.g. megaloblastic anaemia stemming from Vitamin B_{12} deficiency and pernicious anaemia.

In cases of inflammatory conditions or malignancy, iron is deposited in the reticulo-endothelial system and iron mobilisation and utilisation do not occur until the underlying disease is treated.

WARNINGS AND SPECIAL PRECAUTIONS

Notice to diabetics:

Ferrimed® Capsules = 0,1 bread units per capsule,

Ferrimed® Syrup = 0,2 bread units per 5 ml syrup.

DOSAGE AND DIRECTIONS FOR USE

Ferrimed® Capsules:

Therapeutic dose: Two to four capsules (100 mg to 200 mg elemental iron, and 300 µg to 600 µg folic acid) per day or as recommended by a medical practitioner.

Supplementary dose: One to two capsules (50 mg to 100 mg elemental iron, and 150 µg to 300 µg folic acid) per day.

The capsules must be taken in divided doses with meals.

Ferrimed® Syrup	**Dosage Regimen**
Adults	Initially 25 mg to 50 mg elemental iron (2,5 ml to 5 ml syrup) per day increased with 25 mg to 50 mg (2,5 ml to 5 ml) increments to 200 mg (20 ml syrup) per day. The syrup should be taken in two to three divided doses per day, with meals.
Children (6 – 12 years)	25 mg to 125 mg elemental iron (2,5 ml to 12,5 ml syrup) (3 mg elemental iron/kg body weight) per day. The syrup should be taken in one or two divided doses per day, with meals.
Children (2 – 5 years)	15 mg to 50 mg elemental iron (1,5 ml to 5 ml syrup) (3 mg elemental iron/kg body weight) per day. The syrup should be taken in one or two divided doses per day, with meals.
Infants (6 months – 2 years)	Up to 6 mg elemental iron/kg body weight per day. The syrup should be taken in 3 to 4 divided doses with feeds.
Infants (under 6 months)	10 mg to 25 mg elemental iron (1 ml to 2,5 ml syrup) per day. The syrup should be taken in 3 to 4 divided doses with feeds. The dose must take into

	account any supplemental iron contained in the formulation.
Low birth weight infants or infants with low iron stores	Initially 2 mg/kg body weight per day, decreased gradually to 1 mg/kg body weight per day

SIDE EFFECTS

The oral administration of iron preparations may cause gastro-intestinal irritation and abdominal pain with nausea and vomiting. Other gastro-intestinal effects may include either diarrhoea or constipation. The faeces may be coloured black. Lassitude and headache may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

(See **SPECIAL PRECAUTIONS and SIDE EFFECTS)**

Acute iron overdose can be divided into four stages.

In the first phase of acute iron overdosage, which occurs up to 6 hours after oral ingestion, gastro-intestinal toxicity, notably vomiting and diarrhoea, predominates. Other effects may include cardiovascular disorders such as hypotension and tachycardia; metabolic changes including acidosis and hyperglycaemia; as well as central nervous system depression ranging from lethargy to coma. Patients with mild to moderate poisoning do not generally progress past this first phase.

The second phase may occur at 6 to 24 hours after ingestion and is characterised by a temporary remission or clinical stabilisation.

In the third phase gastro-intestinal 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 gastro-intestinal obstruction and possibly late hepatic damage.

In treating acute iron poisoning, speed is essential to block absorption of iron from the alimentary tract. Emesis or lavage should be considered and serum-iron concentrations may be an aid to estimating the severity of the poisoning. Chelation therapy with desferrioxamine, according to the instructions on the package insert, may be necessary.

Treatment is symptomatic and supportive.

IDENTIFICATION

Ferrimed® Capsules: The capsule has an opaque blue cap, with an opaque brown body and contains a milk chocolate-coloured fine powder speckled with deeper brown granules.

Ferrimed® Syrup: A clear, brown, viscous solution, having a creamy vanilla odour.

PRESENTATION

Ferrimed® Capsules: Securitainer containing 60 or 120 capsules.

Ferrimed® Syrup: 100 ml amber glass bottle with a dropper (marked in milliliters) and a medicinal spoon.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a dark, dry place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

Ferrimed® Capsules: H840 (Act 101 of 1965)

Ferrimed® Syrup: H842 (Act 101 of 1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

HEALTHCARE PARK

WOODLANDS DRIVE

WOODMEAD 2191

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