1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

Ferrimed® D.S. Chewable Tablets

COMPOSITION

Ferrimed® D.S. Chewable Tablets:

Each tablet contains 100 mg elemental iron as iron (III)-hydroxide polymaltose complex

Sugar-free

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® D.S. Chewable Tablets= 0,04 bread units per tablet.

DOSAGE AND DIRECTIONS FOR USE

Ferrimed® D.S. Chewable Tablets:

Therapeutic dose: Chew or swallow one to two tablets (100 mg to 200 mg elemental iron) per day.

The tablets must be taken in divided doses with meals.

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® D.S. Chewable Tablets: Brown and white speckled tablet.

PRESENTATION

Ferrimed® D.S. Chewable Tablets: Carton containing 30 or 90 tablets in blister packs.

STORAGE INSTRUCTIONS

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

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

Ferrimed® D.S. Chewable Tablets: L/8.3/201

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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