1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS:

S0

PROPRIETARY NAME AND DOSAGE FORM

STAALDRUPPELS DM (solution)

COMPOSITION:

Each 20 ml of STAALDRUPPELS DM SOLUTION contains: 3,00 g Ferric chloride

Excipients:

Purified water

Sugar free

CATEGORY AND CLASS:

A: 8.3 Erythropoietics

PHARMACOLOGICAL ACTION:

Erythropoietic and styptic

INDICATIONS:

STAALDRUPPELS may be used for iron-deficiency anaemias. It is also effective in stopping bleeding resulting from minor cuts and wounds.

CONTRA-INDICATIONS:

NOT FOR USE IN CHILDREN.

STAALDRUPPELS should not be given to patients receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency unless iron deficiency is also present.

WARNING:

Prolonged administration of doses in excess of those recommended may result in iron overload.

In patients receiving oral iron therapy additional parenteral administration of iron may result in an iron overloading and toxicity.

DOSAGE AND DIRECTIONS FOR USE:

10 – 15 drops in a wineglassful of water three times daily.

As a styptic for cuts and wounds

Apply a few drops over the wound.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Therapeutic doses of iron may cause gastro-intestinal discomfort, diarrhoea, and vomiting. Continued administration may sometimes cause constipation. Local application of ferric chloride may cause permanent discolouration of the skin.

The absorption of iron salts and tetracyclines is diminished when they are taken concomitantly by mouth. If treatment with both drugs is required, the iron salts should be administered 3 hours before or 2 hours after the tetracycline. The absorption of iron salts is

also decreased in the presence of antacids or when taken with tea. Iron salts appear to reduce the effects of penicillamine.

Care should be taken when given to patients with iron-storage or iron-absorption diseases, haemoglobinopathies, or existing gastro-intestinal disease.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Large doses of iron may have irritant and corrosive effects on the gastro- intestinal mucosa and necrosis and perforation may occur; stricture formation may subsequently follow. Symptoms, which may not appear for several hours, include epigastric pain, diarrhoea, vomiting and haematemesis. Circulatory failure may follow if the diarrhoea and haemorrhage are severe.

Hours or days later, after apparent recovery, metabolic acidosis, convulsions, and coma may occur. If the patient survives, symptoms of acute liver necrosis may develop and may lead to death due to hepatic coma. In treating iron poisoning, speed is essential to block absorption of iron from the alimentary tract. A dose of as little as 1 g should be considered toxic in children. The following procedure has been recommended: Inject intramuscularly 2 g of desferrioxamine mesylate dissolved in water for injections; wash out the stomach with a 1% solution of sodium bicarbonate; give 5 g of desferrioxamine mesylate in 50 - 100 ml of water by mouth, or by stomach tube, if necessary, to chelate any iron left in the intestine and prevent further absorption; give desferrioxamine mesylate by intravenous infusion at a rate of not more that 15 mg per kg body weight per hour, with a maximum dosage of 80 mg per kg in 24 hours, if necessary repeat intramuscular injections of 2 g of desferrioxamine mesylate every 12 hours. If desferrioxamine is not available, empty the stomach immediately by emesis and lavage using a 1 to 5% solution of sodium bicarbonate, and leave about 300 ml of the solution in the stomach.

Fluid loss should be replaced by the intravenous administration of compound sodium lactate injection or sodium chloride and dextrose injection. Exchange transfusion may be necessary in severe cases.

IDENTIFICATION:

Clear, yellowish-brown solution.

PRESENTATION:

20 ml is packed in a clear round polyvinyl chloride bottle sealed with a black polypropylene screw on cap lined with an expanded polyethylene liner and a low density polyethylene opaque medicine measure overcap. The bottle is placed in an outer cardboard carton.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

H836 (Act 101/1965)

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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Date of the most recent amendment to the professional information as approved by the Authority: 19 October 2007

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