1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

AUTRIN CAPSULES

COMPOSITION

Each capsule of AUTRIN CAPSULES contains:

Ferrous fumarate	349,755 mg
Ascorbic acid	150 mg
Intrinsic Factor Concentrate	75 mg
Folic acid	2 mg
Vitamin B_{12}	15 µg

Excipients:

Erythrosine (FD&C Red No. 3/C.I. 45430), gelatin, indigo carmine (FD&C Blue No. 2/C.I. 73015), light liquid paraffin, magnesium stearate, maize starch, sodium lauryl sulphate

Sugar free

CATEGORY AND CLASS

A 8.3 Erythropoietics (Haematinics)

PHARMACOLOGICAL ACTION

AUTRIN CAPSULES are used for the treatment of anaemias as indicated below. It contains the common substances used in the prevention and treatment of anaemic conditions.

INDICATIONS

Indicated for the treatment and maintenance of common anaemias, including iron-deficient anaemias, megaloblastic anaemias of pregnancy, pellagra and those of nutritional origin. All of the other means that are recognised as suited to the treatment of these anaemias should also be employed. If cases prove resistant to this form of therapy, further exploration of the aetiology and additional therapeutic measures should be instituted.

CONTRAINDICATIONS

AUTRIN CAPSULES is contraindicated in:

- Patients with hypersensitivity to the actives or to any of the excipients in AUTRIN CAPSULES (see COMPOSITION).
- Symptoms of iron intolerance.

WARNINGS AND SPECIAL PRECAUTIONS

Prolonged administration in excess of the recommended dose as prescribed by the physician (one capsule per day) may result in iron overload. Iron overloading and toxicity may occur in patients receiving both oral and parenteral administration of iron.

Some patients affected with pernicious anaemia may not respond to orally administered Vitamin B_{12} with intrinsic factor concentrate, as contained in AUTRIN CAPSULES, and there is no known way to predict which patients will respond or which patients may cease to respond. Periodic examinations and laboratory studies of pernicious anaemia patients are essential and recommended.

Folic acid, as contained in AUTRIN CAPSULES may obscure pernicious anaemia in that the peripheral blood picture may revert to normal while neurological manifestations may remain progressive.

AUTRIN CAPSULES should not be relied on to correct the serious folic acid deficiency characterising sprue or the malabsorption syndromes. In these conditions therapeutic amounts of folic acid should be administered.

Excessive doses of iron preparations may lead to toxicity in children.

Iron salts, as contained in AUTRIN CAPSULES 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. Care should be taken when given to patients with iron-storage or iron-absorption diseases, haemoglobinopathies, or existing gastrointestinal disease.

INTERACTIONS

Iron salts and tetracycline absorption is diminished if taken concomitantly by mouth. Iron salts, as contained in AUTRIN CAPSULES should be administered 3 hours before or 2 hours after the tetracycline.

Concomitant ingestion of antacids and tea will also decrease the absorption of iron salts, as contained in AUTRIN CAPSULES.

Iron salts, as contained in AUTRIN CAPSULES may reduce the effects of penicillamine.

Quinolone anti-infective medicine absorption is diminished if taken concomitantly by mouth

with iron salts, as contained in AUTRIN CAPSULES. Oral preparations should not be administered within two hours of quinolone medicines .

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

One capsule daily, with or after meals, will treat and maintain the average uncomplicated case of anaemia.

SIDE EFFECTS

Adverse effects of iron administered in therapeutic doses may include gastrointestinal discomfort, diarrhoea, vomiting, constipation.

Side effects may be reduced by taking the medication with or immediately after food.

As a result of iron therapy stools may become darkened or black in colour.

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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Symptoms of overdosage can be any of those described under SIDE EFFECTS above.

Treatment

If any symptoms of intolerance occur, AUTRIN CAPSULES should be temporarily or permanently discontinued.

In acute poisoning desferrioxamine should be administered under the direction of a physician but preferably should not be administered during the first trimester of pregnancy. Alternatively, and preferably in the treatment during pregnancy and lactation, empty the stomach by inducing emesis using a 1 % to 5 % solution of sodium bicarbonate lavage.

Fluid loss should be replaced by the IV administration of compound sodium lactate injection or NaCl and dextrose injection.

A dose of as little as 1 g of iron should be considered toxic in children. Speed is essential here to block the absorption of iron.

IDENTIFICATION

Red, two piece hard shell, size 0 capsule, uniform in colour, size and shape, imprinted "AUTRIN" on one half in grey ink.

PRESENTATION

30 or 100 capsules are packed in a clear polyvinylchloride/polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep the blisters in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H689 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE APPLICANT

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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

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