1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

a) Product Name : LYCOFER CAPSULES

b) Strength

Each capsule contains:

Sodium Feredetate BP 231.0 mg

(Eq. to 33.0mg of elemental Iron)

Folic Acid BP 5.0mg

Cynocobalamin (Vit. B12) BP 15.0 mcg

Zinc Sulphate monohydrate USP

Eq. to elemental Zinc 5.0mg

c) Pharmaceutical Dosage form

Solid Oral Dosage Form (ORAL CAPSULES)

2. Quality and Quantitative Composition

a) Qualitative declaration

Sodium Feredetate BP

Folic Acid BP

Cynocobalamin (Vit. B12) BP

Zinc Sulphate monohydrate USP

b) Quantitative declaration

Each capsule contains

Sodium Feredetate BP 231.0 mg

(Eq. to 33.0mg of elemental Iron)

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Zinc Sulphate monohydrate USP

Eq. to elemental Zinc 5.0mg

3. Pharmaceutical form visual description of the appearance of the product

Scarlet/Scarlet coloured, hard gelatin capsules containing brown coloured powder.

4. Clinical Particulars

4.1 Therapeutic indications

Sodium Feredetate is indicated for Iron deficiency anaemia, Iron is vital for formation of new red blood cells and hemoglobin, a substance that gives these cells the ability to transport oxygen. Folic Acid and Vitamin B12 correct the deficiency of vitamin B. Zinc treatment of zinc deficiency.

4.2 Posology and method of administration:

Adults: 1-2 Capsules per day or as directed by the physician.

Children over 12 year: 1 capsule daily

Elderly (Over 65 year) as for adults.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special warning and precautions for use

Do not take Lycofer Capsules on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of Interactions

Tetracycline, antacids, penicillamine, milk-decrease absorption.

Chloramphenicol may delay response to iron therapy.

Vitamin C may aid absorption of oral iron.

4.6 Pregnancy and lactation

No clinical data on exposed pregnancies are available.

4.7 Effects on ability to drive and use machine

None stated.

4.8 Undesirable effects

Since iron in sodium feredetate is stable and passes the acidic medium of the stomach intact, most of the common adverse effects associated with the conventional iron salts. E.g. G.I. irritation, nausea, vomiting, bloating, are either absent or very mild.

However, some patients have occasionally complained of nausea or mild diarrhea in the early stages of administration. In such cases, it has been found that if administration is withdrawn for a short period,

these symptoms disappear and subsequently the patients tolerates further doses which should be on a somewhat reduced scale.

Some of the normal individual who have taken LYCOFER capsules at twice the recommended dosage have experienced mild diarrhea. This should be taken into account if dosage is increase much higher than the recommended scale.

4.9 Overdose

Initial symptoms of iron overdosage include, nausea, vomiting diarrhea, abdominal pain, heamatemesis, rectal bleeding, lethargy and circulatory collapse, hyperglycaemia and metabolic acidosis may occur.

5. Pharmacological Properties:

5.1.1 Pharmacodynamic Properties

Mechanism of Action: Sodium Feredetate is stable in an acidic environment and hence no dissociation of Sodium Feredetate complex takes place in the stomach. It is only when it enters the duodenum that dissociation of sodium feredetate takes place into EDTA and Iron. Iron absorption begins where iron is made available to the mucosal cells. The free EDTA then acts as a shuttle and picks up more iron, copper, zinc, from the food and delivers it to the mucosa I cells.

Pharmacokinetic properties

Absorption: When sodium feredetate is ingested, it passes the stomach intact subsequently it arrives in the duodenum and small intestine, where the absorption of iron and minerals takes place. The mucosal cells that line the duodenum and small intestine possess a remarkable capability to split Sodium Feredetate (NaFeEDTA) into iron and EDTA.

Distribution: Post absorption distribution of elemental iron is as follows: 60 % to 70 % is incorporated into haemoglobin and most of the remainder is present in storage forms, either as ferritin or haemosiderin. A further 4% is present in myoglobin and heam-containing enzymes, or bound to transferrin in plasma.

Excretion: The EDTA molecule stays behind, and 95% (EDTA) is excreted in faeces. EDTA passes through the body unchanged. A small part (5%) of this split-off EDTA enters the blood circulation, but is quantitatively excreted by the kidneys within 24 hours.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical Particulars:

6.1 List of excipients :

Di-calcium phosphate BP

Maize Starch

Magnesium Stearate

Purified Talc

Sodium Lauryl sulphate

Colloidal anhydrous silica

Hard gelatin capsule shell

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life: 24 Months.

6.4 Special precautions for storage

Store at temperature not exceeding 30^0 C in a dry place, Protect from light.

Keep out of reach of children.

6.5 Nature and contents of container

10 Tablets in Strip such 3 Strip Pack in carton along with pack insert.

6.6 Special precautions for disposal <and other handling>

Not Applicable

7.0 Applicant/Manufacturer

COOPER PHARMA LIMITED

C-3, Industrial Area Selaqui,

Dehradun-248197, Uttarakhand, India

WHO-GMP Certified Company