1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

a) Product Name : LYCOFER SYRUP

b) Strength

Each 15ml contains:

Sodium Feredetate BP

equivalent to elemental Iron 33 mg

Folic Acid BP 5 mg

Cyanocobalamin (Vit. B12) BP 15 mcg

In a flavoured syrupy base q. s.

c) Pharmaceutical Dosage form

Liquid Dosage Form (ORAL SYRUP)

2. Quality and Quantitative Composition

a) Qualitative declaration

Sodium Feredetate BP

Folic Acid BP

Cynocobalamin (Vit. B12) BP

b) Quantitative declaration

Each 15ml contains

Sodium Feredetate BP

Eq. to elemental Iron 33.0mg

Folic Acid BP 5.0mg

Cynocobalamin (Vit. B12) BP 15.0 mcg

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

Brown to light brown colour liquid filled in amber colour PET bottles.

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.

4.2 Posology and method of administration:

Lycofer syrup

Adults: 15ml once or twice times daily. Elderly (over 65 years): As for adults. Infants (including premature infants) up to I year: 2.5ml once or twice daily, somewhat smaller doses should be used initially.

1 to 5 years: 2.5ml two times daily.

6 to 12 years: 5ml two times daily.

Children over 12 years: 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

Take between meals for maximum absorption; may be taken with food if G I upset occurs; do not take with milk or antacids or eggs, if these have been eaten, delay administration for an hour: for best absorption give with fruit juice.

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 SYRUP 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 :

Sorbitol Solution 70% BP

Sodium Methylhydroxybenzoate BP

Sodium Propylhydroxybenzoate BP

Sodium Saccharin BP

Sodium Benzoate BP

Xanthan Gum BP

Citric Acid monohydrate BP

Invert sugar syrup BP

Sodium hydroxide BP

Essence mixed fruit In-House

Essence sweet orange No.1 In-House

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life: 36 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

200ml Amber Colour PET bottle packed in a 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