Summary of Product Characteristics

1 **Name of** The **Medicinal Product**
Hemoton S Syrup

2 **Qualitative and Quantitative**
Composition Each l00ml
contains:
Ferric Ammonium Citrate B.P.C.....900mg
Folie Acid B.P. 10mg
Thiamine Hydrochloride B.P (Vit Bl) 20mg
Pyridoxine Hydrochloride B.P (Vit B6). 40mg
Nicotinamide B.P..... 200mg
Liquid Glucose..... q.s

3 Pharmaceutical
Form Syrup

4 **Clinical** Particulars

4.1 Therapeutic Indications

Iron deficiency anemia, anemia in pregnancy, anemia in children, anemia due to chronic blood loss, worm infestations, infection or surgery.

4.2 Posology and Method of Administration

The following doses should be administered 2 or 3 times daily after meals or as directed by the physician. Usual dose for:
Adults : l5ml (3 teaspoonful)
Children: 5 to 10ml (1 to 2
teaspoonful) Infants: 3 to 5ml (1/2
to 1 teaspoonful)

4.3 Contraindications

Hemoton-S Syrup is contraindicated in the following cases; Hypersensitivity to any of the ingredients, patients with iron intolerance, patients receiving repeated blood transfusions, patients with iron-absorption disease, or existing gastrointestinal disease.

4.4 Special Warnings and Precautions of Use

Hemoton-S Syrup should be used with caution in patients with history of peptic ulcer, acute inflammatory disease of the bowel, renal failure, hyperthyroidism and to patients with impaired liver function

4.5 Interaction with Other Medicinal Products and Other Forms of Interactions Drug—Drug Interactions

Iron Supplements can interact with multiple drugs, primarily affecting absorption or efficacy: Antacids / Proton Pump Inhibitors (PPIs) / H2 Blockers Effect: Reduce iron absorption due to increased gastric pH. Recommendation: Administer iron at least 2 hours before or after antacids. Calcium Supplements / Milk Products: Effect: Calcium binds iron in the gut, reducing absorption. Recommendation: Take iron separately from calcium-containing products. Tetracyclines (e.g., doxycycline, tetracycline): Effect: Iron forms insoluble complexes with tetracyclines decrease absorption of both drugs. Recommendation: Separate dosing by 2—4 hours. Fluoroquinolones (e.g., ciprofloxacin, levofloxacin) Effect: Similar chelation decrease antibiotic absorption. Recommendation: Take iron 2—4 hours apart. Levothyroxine: Effect: Iron may reduce thyroid hormone absorption. Recommendation: Separate dosing by 4 hours. Penicillamine (for Wilson's disease): Effect: Iron may reduce penicillamine absorption. Recommendation: Separate by at least 2 hours. Methyldopa / Levodopa: Effect: Iron can decrease CNS uptake of these drugs. Recommendation: Administer iron at a different time. Drug—Nutrient / Food Interactions: Tea, Coffee, Chocolate, and High-Fiber Foods: Effect: Polyphenols, tannins, and fiber bind iron decrease absorption. Recommendation: Avoid taking iron with these foods; take on an empty stomach if tolerated. Vitamin C (Ascorbic Acid): Effect: Enhances absorption of non-heme iron. Recommendation: Can be co-administered; some iron formulations already include vitamin C. Other Forms of Interactions Folic Acid: May mask symptoms of vitamin B12 deficiency if taken in high doses. Interaction with anticonvulsants (e.g., phenytoin, phenobarbital): These drugs may reduce folate levels supplementation may be required. Iron Overload Conditions: Patients with hemochromatosis or chronic transfusions may experience toxicity if iron supplementation is taken without monitoring.

4.6 Fertility, Pregnancy and Lactation Pregnancy:

Iron and folic acid supplementation is recommended during pregnancy to prevent iron-deficiency anemia and support fetal development. Folic acid is essential in the first trimester to reduce the risk of neural tube defects in the fetus. Clinical experience: No evidence suggests that iron (III) hydroxide polymaltose or folic acid at therapeutic doses is teratogenic. Recommendation: Can be safely administered under medical supervision during pregnancy. Precautions should be taken when Iron overdose during pregnancy can be harmful; dosing should be individualized according to hemoglobin and iron status. Regular monitoring of hemoglobin and ferritin is recommended for pregnant or lactating women on prolonged supplementation.

Lactation:
Iron is excreted in small amounts in breast milk but is generally considered safe for the nursing infant. Folic acid passes into breast milk and is beneficial for infant growth. Supplementation is recommended in lactating mothers with anemia.

Fertility:
No adverse effects on fertility have been reported with therapeutic use of iron or folic acid. Folic acid supplementation may support preconception health.

4.7 Effects of Ability to Drive and Use Machines

There is no effect on the ability to drive and use machines.

4.8 Undesirable Effects

Heart burn, Nausea and vomiting, upper gastric discomfort, constipation or diarrhea may occur rarely in patients sensitive to iron preparations. Side effects may be reduced by administration with or after food. Ferric Ammonium Citrate may cause blackening of stools.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important.It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the marketing authorisation holder, or, if available, via the national reporting system.

4.9 Overdose

Iron Overdose resulted in Gastrointestinal irritation (nausea, vomiting, abdominal pain, diarrhea), hematemesis, melena, hypotension, tachycardia, lethargy, metabolic acidosis, shock. In Severe cases can lead to multi-organ failure, hepatic necrosis, coma, or death, especially observed in children who accidentally ingest iron-containing products. Symptoms usually appear within 6 hours after ingestion. Excessive doses of Folic Acid may cause mild gastrointestinal disturbances (nausea, bloating, flatulence) but serious toxicity is rare. Management of Overdose can be immediate action with induce vomiting or perform gastric lavage if ingestion is recent. Supportive care is required with monitoring vital signs, hydration, and electrolytes. Specific therapy includes deferoxamine can be administered intravenously or intramuscularly in severe iron poisoning. The hospitalization is required in moderate to severe cases, especially in children with continuous monitoring of liver function tests, complete blood count, serum iron levels, and coagulation profile may be necessary in severe overdose. Precaution includes educate patients on correct dosing to prevent accidental overdose.

5- Pharmacological Properties

Pharmacodynamics

Properties

Pharmacodynamic

Group and ATC Code

Pharmacotherapeutic group: Iron in other combinations (Iron,

Multivitamins and Folic acid) ATC code: B03AE02

Mechanism of action

Hemoton-S Syrup contains inorganic iron as Ferric Ammonium bitrate which is easily absorbed and well tolerated. In the recommended dose Ferric Ammonium bitrate achieves a rapid rise in haemoglobin level. The other components of the Vitamin B-complex group are important for various metabolic functions of the body

Pharmacodynamic Effect

Ferric Ammonium bitrate: Replenishes iron
fo rhemoglobin synthesis. Folic Acid: DNA
synthesis, prevents megaloblastic anemia.

Thiamine (Bl): Carbohydrate metabolism,
nerve function. Pyridoxine (B6): Amino acid
metabolism, neurotransmitter synthesis.

Nicotinamide (B3): Coenzyme in oxidation-reduction reactions, cellular energy metabolism.

Synergistic effect: Combined supplementation corrects both anemia and vitamin deficiencies, supports general health.

5.1 Pharmacokinetic Properties

Iron and B-vitamins absorbed in the small intestine, absorption of iron enhanced by fasting. B-vitamins are widely distributed whereas iron incorporated into hemoglobin and stored in ferritin. Vitamins metabolized in liver while iron is not metabolized and incorporated into red blood cells. Water-soluble vitamins excreted in urine, excess iron minimally excreted.

5.2 Preclinical Safety Data

Non-clinical data derived from the literature and class effects reveal no special hazard for humans at the intended clinical exposures based on conventional studies

6- Pharmaceutical

Particulars 6.1- List of

Excipients

Methyl Paraben
Propyl Paraben
Sodium benzoate
Carboxymethyl cellulose sodium
Citric acid
Refined sugar
Liquid glucose
Caramel Color
Chocolate Flavor
Purified Water

6.2- Incompatibilities

Not applicable

6.3 Shelf Life

24 Months

6.4 Special Precautions for Storage

No Special Requirements

6.5- Nature and Contents of Container

Hemoton S Syrup 250m1 is filled in 250m1 amber plastic bottle.

6.6 Special Precautions for Disposal

Please refer to section 6.4.

7- Marketing Authorization Holder and Manufacturing Site Addresses

Indus Pharma Private Limited
Plot No. 26-27 & 63-67 Sector 27 Korangi Industrial Area, Karachi - 74900 8-

8- Marketing Authorization Number

H2001/0432

9- Date of Registration

25"' July 1990

10- Date of Revision of the Text

17th June 2026