National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

IRON SYRUP WITH VITAMIN B12 AND FOLIC ACID

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 15 ml contains:

Ferric Ammonium Citrate USP (Eq. to Elemental Iron 32mg)	160mg
Cyanocobalamin BP	7.5 mcg
Folic Acid BP	0.5 mg
Flavoured Syrupy Base	Q.S
Colour: Caramel	

3. PHARMACEUTICAL FORM

Liquid Syrup

4. Clinical particulars

4.1 Therapeutic indications

RON SYRUP WITH VITAMIN B12 AND FOLIC ACID is used for Iron deficiency anemia due to chronic blood loss, hook-worm infestation, inadequate intake of iron, etc. Anemia of pregnancy other dimorphic anemia, lack of apatite, rundown conditions, there are common symptoms of anemia which might be occult initially. Requirements of vitamin in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation. Megaloblastic anemia due to a deficiency of folic acid as may be seen in tropical or non-tropical sprue, in anemia of nutritional origin, pregnancy, infancy, or childhood.

4.2 Posology and method of administration

Adults: - One or two 5ml spoonfuls of IRON SYRUP WITH VITAMIN B12 AND FOLIC ACID two or three times daily, or more at the discretion of the physician.
Elderly: - The normal adult dose is appropriate for the elderly.
Children: - One 5 ml spoonful of IRON SYRUP WITH VITAMIN B12 AND FOLIC ACID two or three times daily, or more at the disacretion of the physician.

4.3 Contraindications

Known hypersensitivity to any of the components in the product is a contraindication

4.4 Special warnings and precautions for use

For pernicious anaemia, an adequate dose must be used and the blood picture must be examined regularly at least every 3 months for 18 months until stabilised, and then annually.

Indiscriminate administration of irondex may mask the precise diagnosis.

Long term treatment with irondex syrup may increase the risk of dental carnes. It is important that adequate dental hygiene is maintained.
Medicines containing sugar should be administered with care to patients with diabetes mellitus.

4.5 Interaction with other medicinal products and other forms of interaction

Persons taking most antibiotics methotrexate and pyrimethamine invalidate folic acid and vitamin B12 diagnostic blood assays. Colchicine para-aminosalicylic acid and heavy alcohol intake for longer than 2 weeks may produce malabsorption of vitamin B12.

4.6 Pregnancy and Lactation

IRON SYRUP WITH VITAMIN B12 AND FOLIC ACID should only be used during pregnancy and breast-feeding after benefit/risk assessment by the physician in charge**.**

4.7 Effects on ability to drive and use machines

No data are available regarding the influence of HEXORANGE on a patient's ability to drive or operate machinery

4.8 Undesirable effects

Cardiovascular: Pulmonary edema and congestive heart failure early in treatment; peripheral vascular thrombosis.

Hematological: Polycythemia Vera

Gastrointestinal: Mild transient diarrhea

Dermatological: Itching; transitory exanthema

Miscellaneous: Feeling of swelling of entire body, Diarrhea, Polycythemia Vera, itching transitory exanthema and Allergic sensitization has been associated.

4.9 Overdose

Symptoms and signs of overdose

Symptoms may include black, tarry stools; blood in vomit; diarrhea; headache; nausea; vomiting.

Treatment of intoxication

Overdosage is unlikely to require treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Iron in other Combination

ATC code: BO3AE

Mode of Action

Iron is an essential constituent of the body, and is necessary for haemoglobin formation and for the oxidative processes of living tissues. Iron and iron salts should be given for the treatment or prophylaxis of iron deficiency anaemias. Soluble ferrous salts are most effective by mouth. Ferrous fumarate is an easily absorbed source of iron for replacement therapy. It is a salt of ferrous iron with an organic acid and is less irritant to the gastro-intestinal tract than salts with inorganic acids.

Cyanocobalamin, Vitamin B12, maintains healthy blood cells and nervous tissue. It also aids in the synthesis and replication of DNA, the genetic substance of every cell.

The recommended daily allowance of folic acid, helping the body to produce and maintain cells.

5.2 Pharmacokinetic properties

In the acid conditions of the gastric contents, ferrous fumarate is dissociated and ferrous ions are liberated. These ions are absorbed in the proximal portion of the duodenum.
The ferrous iron absorbed by the mucosal cells of the duodenum is oxidised to the ferric form, and this is bound to protein to form Ferritin.
Ferritin in the mucosal cells releases iron into the blood, where it is bound to transferrin and passed into the iron stores - liver, spleen, and bone marrow.
These stores are a reserve of iron for synthesis of haemoglobin, myoglobin, and iron containing enzymes.
Iron is lost from the body through loss of cells in urine, faeces, hair, skin, sputum, nails, and mucosal cells, and through blood loss.

The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor. Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins. Cobalamins are stored in the liver and excreted in the bile. They are known to cross the placenta.

Folic acid is rapidly absorbed from the proximal part of the gastrointestinal tract following oral administration. It is mainly absorbed in the proximal portion of the small intestine. The naturally occurring folate polyglutamate is enzymatically hydrolysed to monoglutamate forms in the gastrointestinal tract prior to absorption. The peak folate activity in blood after oral administration is within 30 to 60 minutes. Enterohepatic circulation of folate has been demonstrated. Tetrahydrofolic acid and its derivatives are distributed in all body tissues. Folate is actively concentrated in the CSF at about 0.016 to 0.021 mg/ml while the normal erythrocyte level is about 0.175 to 0.316 mg/ml. The liver contains half of the total body stores of folate and is the principal storage site. Folic acid once absorbed is acted upon by hepatic dihydrofolate reductase to convert to its metabolically active form which is tetrahydrofolic acid. Following absorption of 1 mg or less, folic acid is largely reduced and methylated in the liver to N-5 methyltetrahydrofolic acid, which is the main transporting and storage form of folate in the body. Larger doses may escape metabolism by the liver and appear in the blood mainly as folic acid. Following oral administration of single 0.1 to 0.2 mg doses of folic acid in health adults, only a trace amount of the drug appears in urine. Following administration of large doses, the renal tubular reabsorption maximum is exceeded and excess folate is excreted unchanged in urine. Small amounts of orally administered folic acid have been recovered from faeces. About 0.05 mg/day of normal body folate stores is lost by a combination of urinary and faecal excretion and oxidative cleavage of the molecule. Folic acid is also excreted in the breast milk.

5.3 Preclinical safety data

Not Applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose BP
Sodium Methyl Paraben BP
Sodium Propyl Paraben BP
Croscarmellose Sodium BP
Sorbitol Solution BP
Glycerin BP

Colour Caramel IH
Ess. Liquid Orange Juicy F1507M
IH
Sodium Hydroxide BP
Colour Supra Erythrosine IH
Ess Liquid Sweet Orange IH
Ess Liquid Black Current IH
Purified Water BP
Citric Acid Anhydrous BP

6.2 Incompatibilities

Not known

6.3 Shelf life

30 months from the date of manufacturing

6.4 Nature and contents of container<and special equipment for use, administration or implantation>

Packing: 200 ml Amber Coloured Glass Bottle

Primary Packing: Amber Coloured Glass Bottle of 200 ml sealed with 25 mm Aluminium cap along with 15 ml measuring cup.

Secondary Packing: Such 1 bottle is packed in printed carton along with package insert.

6.5 Special precautions for disposal <and other handling>

None

7 <APPLICANT/MANUFACTURER>

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