1. Name of the medicinal product

Ferro – B Syrup

2. Qualitative and quantitative composition

Each 5ml syrup contains:

Green Iron and Ammonium Citrate B.P.C. 1954 - 200mg

Vitamin B_1 BP 2.0 mg

Riboflavin BP 0.5 mg

Vitamin B_{12} BP 2.5 mcg

Nicotinamide BP 5.0 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Coffee-brown coloured viscous liquid without any visible impurities and having a characteristic flavour and taste.

4. Clinical particulars

4.1 Therapeutic indications

Ferro-B Complex Syrup is a combination preparation containing Iron and Vitamin B Complex. It is indicated for the prevention of Vitamin B and Iron deficiency in such conditions as:

- Nutritional Deficiency (restriction)
- Pregnancy
- Parasitic infection
- Chronic haemorrhage

4.2 Posology and method of administration

Adults and Children Over 12 years:

Four to eight 5ml spoonfuls daily

Children 6 – 12 years:

Two to three 5ml spoonfuls daily

Children 2 – 6 years:

One 5ml spoonful daily OR as directed by a doctor

4.3 Contraindications

Ferro-B Complex Syrup should Not be used by patients hypersensitive to any of the ingredients, or those with iron overload. Other contraindications are paroxysmal nocyurnal haemoglobinuria, haemosiderosis, haemochromatosis, active peptic ulceration, repeated blood transfusions, regional enteritis and ulcerative colitis.

4.4 Special warnings and precautions for use

Care should be taken in patients who may develop iron overload such as those with haemochromatosis, haemolytic anaemia or red cell aplasia. Failure to respond to treatment may indicate other causes of anaemia and should be further investigated. Absorption of iron

may be impaired by penicillamine and antacids. Consequently, these preparations should be taken (orally) several hours apart.

4.5 Interaction with other medicinal products and other forms of interaction
Oral iron reduces the absorption of tetracyclines.

4.6 Pregnancy and lactation
Definite evidence of iron deficiency during the first trimester of pregnancy is required, before Ferro-B Complex is taken. Otherwise it should be avoided. Not for megaloblastic anaemia in pregnancy since this is due to folic acid deficiency.
Ferro-B Complex should NOT be used in lactating mothers.

4.7 Effects on ability to drive and use machines
None anticipated.

4.8 Undesirable effects
Gastrointestinal disorders like gastrointestinal discomfort, anorexia, nausea, vomiting, constipation, diarrhoea and darkening of the stools may occur. Rarely allergic reactions to the preservatives may occur.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose
Symptoms and signs of overdosage include vomiting and diarrhoea and abdominal pain within the first one hour. This may be followed by cardiovascular collapse with coma. After this, improvement and recovery may follow in some patients. However, in most patients, after 16 hours, deterioration may occur involving pulmonary oedema, convulsions, hypothermia, severe shock, metabolic acidosis or hypoglycaemia.

Treatment

Treatment of overdosage includes immediate induction of vomiting followed by parenteral I.M injection of desferrioxamine mesylate and then gastric lavage.

5. Pharmacological properties

5.1 Pharmacodynamic properties
The following account summarises the pharmacological effects of the vitamins and iron in Ferro-B Complex and describes the conditions caused by deficiency of these.

Vitamin B_1 (Thiamine)

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability

and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

Vitamin B_2 (Riboflavine)

Riboflavine is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide which act as co-enzymes in the respiratory chain and in oxidative phosphorylation. Riboflavine deficiency presents with ocular symptoms, as well as lesions on the lips and at angles of the mouth.

Vitamin B_{12} (Cyanocobalamin)

Vitamin B_{12} is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B_{12} interferes with haemopoiesis and produces megaloblastic anaemia.

Nicotinamide

The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adenine dinucleotide phosphate) include the degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency produces pellagra and mental neurological changes.

Iron

Iron, as a constituent of haemoglobin, plays an essential role in oxygen transport. It is also present in the muscle protein myoglobin and in the liver. Deficiency of iron leads to anaemia.

5.2 Pharmacokinetic properties

The following account describes the absorption and fate of each of the active constituents of Ferro-B Complex Syrup.

Vitamin B_1 (Thiamine)

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

Vitamin B_2 (Riboflavine)

Riboflavine is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine. In the body riboflavine is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

Vitamin B_{12} (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B_{12} showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

Nicotinamide (Nicotinic Acid Amide)

Nicotinic acid is absorbed from the gastro-intestinal tract, is widely distributed in the body tissues and has a short half-life.

Ferrous Fumarate (Iron)

Iron is absorbed chiefly in the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and if the iron is in the ferrous state as in ferrous fumarate. In conditions of iron deficiency, absorption is increased and, conversely, it is decreased in iron overload. Iron is stored as ferritin.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients
Sodium Benzoate
Methyl Paraben
Propyl Paraben
Sodium Saccharin (mesh 40 - 80)
Sucrose
Hydroxyethyl Cellulose (Natrosol HHX250)
Ponceau 4R Red 7 Colour (E124)
Tartrazine Yellow FD & C Yellow 5 Colour (E102)
Brilliant Blue Colour FD & C Blue 1(E133)
Vanilla Flavour Liquid
Disodium Hydrogen Phosphate Dodecahydrate
Citric Acid Anhydrous
Alcohol 90% (Rectified Spirit)
Potassium Sorbate
Aniseed oil

6.2 Incompatibilities
No major incompatibilities are known.

6.3 Shelf life
24 months, as packaged for sale.

6.4 Special precautions for storage
Store in a cool dry place at a temperature not exceeding 25°C.

Protect from light.

DECLARATION BY THE APPLICANT

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority of the EAC Partners States.

I further agree that I am obliged to follow the requirements of the Partner States Legislations and Regulations, which are applicable to medicinal products.

I also consent to the processing of information provided by the EAC Partner States.

It is hereby confirmed that fees will be paid/have been paid according to the National/Community rules*

Name: DR. DHARMESHBHAI RASIKBHAI PATEL
Position in the company: COMPANY PHARMACIST

Signature: .....

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Date: 25/05/2021

Official stamp:.....

* Note: If fees have been paid, attach proof of payment