MEZRON HAEMOGLOBIN WITH VITAMIN B12 SYRUP

1. Name of the medicinal product

MEZRON HAEMOGLOBIN WITH VITAMIN B12 SYRUP

2. Qualitative and quantitative composition

Each 5ml contains

Haemoglobin 5%w/v

Chelated iron 0.3%w/v

Cyanocobalamin 0.0004%w/v

Malt extract 2%w/v

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Oral Liquid

A dark brown viscous liquid with a faint chocolate flavor

4. Clinical particulars

4.1 Therapeutic indications

MEZRON HAEMOGLOBIN WITH VITAMIN B12 SYRUP
is indicated for

- Iron deficiency anemia due to chronic blood loss, hook-worm infestation, inadequate intake of iron, etc.
- Dimorphic anemia due to deficiency of Iron, Folic Acid, and /or Vitamin B12 (Cyanocobalamin).
- Anemia of pregnancy and lactation.
- Tonic in general weakness, lack of appetite, rundown conditions, and convalescence.
- Post-surgery and other debilitated states.

4.2 Posology and method of administration

For oral administration:

Adults

2 teaspoonfuls 4 times daily

Children (5-12 years)

1 teaspoonful 4 times daily

Children (2-5 years)

1 teaspoonful 2 times daily

4.3 Contraindications

- Primary (idiopathic) or secondary iron storage disease.

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- Anaemia associated with ineffective erythropoiesis, marrow hypoplasia, sideroblastic change, and uncomplicated Cyanocobalamin deficiency.
- Intestinal disease (oral iron may aggravate the severe acute inflammatory intestinal disease and is ineffective in patients with extensive small intestinal disease eg. celiac sprue.) Previous hypersensitivity to any of the ingredients in the syrup.
- Known idiosyncrasy to commonly used excipients.
- Porphyria cutaneatardia.
- Uncontrolled parathyroid disease, and sickle cell patients.

4.4 Special warnings and precautions for use

Care should be taken in patients with iron storage our iron absorption diseases such as haemochromatosis, hemoglobinopathies or existing gastro-intestinal diseases such as inflammatory bowel disease, intestinal structures and diverticulae.

4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the sametime, the effects of **HBeam** Haemoglobin Syrup may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. HBeam Haemoglobin Syrup may interact with the following drugs and products:

- Arsenic trioxide
- Chloramphenicol
- Folic acid
- Furosemide
- Gabapentin
- Hydrochlorothiazide
- Levothyroxine
- Lisinopril

Compounds containing Calcium and Magnesium including antacids and mineral supplements and bicarbonates, carbonates, oxalates or phosphates, may also impair the absorption of iron by the formation of insoluble complexes.

Similarly, absorption of both iron & tetracyclines is diminished when they are taken concomitantly by mouth. If treatment with both drugs is required,a time interval of about 2 to 3 hours should be allowed between them.

- Avoid milk and dairy products atleast for 2 hours.
- Some agents such as Ascorbic Acid & Citric Acid may actually increase the absorption of iron.
- The response to iron may be delayed in patients receiving concomitant parenteral chloramphenicol therapy.
- Iron salts can decrease the absorption of bisphosphonates, fluoroquinolones, levodopa, methyldopa, penicillamine and tetracycline.
- Iron salts may reduce the efficacy of thyroxine.

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4.6 Fertility, pregnancy and lactation

Can be used in Iron deficiency anaemia during Pregnancy and Lactation after considering risk benefit ratio

4.7 Effects on ability to drive and use machines

MEZRON HAEMOGLOBIN WITH VITAMIN B12 SYRUP
has no influence on the ability to drive or use machines.

4.8 Undesirable effects

Heamoglobin

These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

Diarrhea
Swelling
Rapid weight gain
Itching or mild rash
HBeam Haemoglobin Syrup may also cause side-effects not listed here.

Ferric Ammonium Citrate:

In high or toxic doses or poisoning - Gastrointestinal irritation, abdominal pain with nausea, vomiting and either diarrhoea or constipation. Cardiovascular disorders such as hypotension, tachycardia, metabolic changes including acidosis and hypoglycemia. CNS depression ranging from lethargy to coma.

Cyanocobalamin:

No known side effects even with very large doses.

4.9 Overdose

The most sign & Symptoms of overdosage are Gastrointestinal irritation, abdominal pain with nausea, vomiting and either diarrhoea or constipation. Cardiovascular disorders such as hypotension, tachycardia, metabolic changes including acidosis and hypoglycemia. CNS depression ranging from lethargy to coma.

Vomiting is induced immediately followed by parenteral injection of desferroxamine mesylate and then gastric lavage. In the meantime, give milk and/or 5% sodium bicarbonate solution by mouth. Fluid replacement is essential. Other measures include symptomatic management and therapy of metabolic and cardiovascular disorders.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutics group: Hematinic syrup, ATC code: B03AE01

Ferric Ammonium Citrate:

Ferric Ammonium Citrate is one of the best-tolerated iron supplements. It rapidly supplements elemental iron so that iron deficiency is quickly controlled, thus leading to faster correction of anaemia and replenishment of tissue iron stores.

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Cyanocobalamin:

Cyanocobalamin (Vitamin B12) is a complex organo-metallic compound in which a cobalt atom is placed within a corrin ring. It plays an important role in synthesis of DNA and maturation of red cells. It acts as a co-enzyme in certain steps necessary for genetic replication**.**

Pharmacokinetic properties Iron (Ferric Ammonium Citrate):

Iron irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid section of the stomach and by some dietary acids (such as ascorbic acid) and is more readily affected when theiron is in the ferrous state or is part of the haem complex (haem-iron). Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Only about 5 to 15% of theiron ingested in food is normally absorbed.

Most absorbed iron is bound to transferrin and transported to the bone marrow where it is incorporated into haemoglobin; the remainder is contained within the storage forms, ferritin or haemosiderin, or as myoglobin, with smaller amounts occurring in haemcontaining enzymes or in plasma bound to transferrin.

Only very small amounts of iron are excreted as the majority released after the destruction of the haemoglobin molecule is re-used.

Cyanocobalamin:

Cyanocobalamin bind to intrinsic factor,a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastro-intestinal tract. Absorption is impaired inpatients with an absence of intrinsic factor,with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy. Absorption from the gastro-intestinal tract can also occur by passive diffusion.

Cyanocobalamin is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Cyanocobalamin is stored in the liver, excreted in the bile and undergoes extensive enterohepatic recycling; part of an administered dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Cyanocobalamin diffuses across the placenta and also appears in breast milk.

5.3 Preclinical safety data

Toxicology Iron:

Iron is a general cellular poison and is directly corrosive to the GI mucosa.

Cellular toxicity

The absorption of excessive quantities of ingested iron results in systemic iron toxicity. Severe overdose causes impaired oxidative phosphorylation and mitochondrial dysfunction, which can result in cellular death. The liver is one of the organs most affected by iron toxicity, but other organs such as the heart, kidneys, lungs, and the hematologic systems also maybe impaired.

Mild To Moderate Poisoning: Vomiting and diarrhea may occur within 6 hours of ingestion.

Severe Poisoning: Severe vomiting and diarrhea, lethargy, metabolic acidosis, shock, GI hemorrhage, coma, seizures, hepatotoxicity, and late onset GI strictures.

Vitamin B12:

Vitamin B12 is usually considered a non-toxic substance. Even taking it by injection at high doses does not seem to increase the risk for toxicity.

Alcohol:

Even though alcohol contributed to severe toxicity **MEZRON** HAEMOGLOBIN WITH VITAMIN B12 SYRUP contains very low level of alcohol i.e. may not lead to toxicity even during pregnancy. As the National Institute of Health and Clinical Trial Excellence (NICE) recommends that women should avoid alcohol during the 1st trimester, women who chose to drink alcohol are advised to drink no more than 1 – 2 UK units of alcohol once or twice a week. They further state that, "Although there is uncertainty regarding a safe level of alcohol consumption in pregnancy, at this low level there is no evidence of harm to the unborn baby".

6. Pharmaceutical particulars

6.1 List of excipients

Xanthan gum

Ethanol

Methyl paraben

Propyl paraben

Sodium benzoate

Chocolate flavour

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years

6.4 Special precautions for storage

Store below 30°C.

Do not refrigerate or freeze.

6.5 Nature and contents of container

200ml amber-coloured Glass bottles with 28mm plastic caps

6.6 Special precautions for disposal and other handling

No special requirements

7. Manufacturer

Jehyson Healthcare Limited

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8. Marketing authorisation holder

Muchis Healthcare Limited

9. Marketing authorisation number(s)

IN-VIEW

10. Date of first authorisation/renewal of the authorisation

NA

11. Date of revision of the text

NA