

1. NAME OF THE MEDICINAL PRODUCT

AvroHB Haemoglobin Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Haemoglobin	500mg
Malt Extract	100mg
Cyanocobalamin (Vitamin B ₁₂)	20mcg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Liquid.

A viscous brown coloured liquid with a malt taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AvroHB Tonic is indicated for:

- Prevention and treatment of anaemia and Vitamin B12 deficiency states.
- Restoration of blood following debilitating illness
- Restorative tonic in run-down conditions and in convalescence

4.2 Posology and method of administration

Method of administration: Oral

Dosage and Administration

Adults and children above 12 years: 10ml four times daily.

Children:

2 - 5 years: 5ml two times daily.

6 - 12 years: 5ml four times daily.

Doses should be taken with or before meals.

May be diluted with water if required.

Shake the bottle well before use.

4.3 Contraindications

AvroHB is contraindicated in patients who are hypersensitive to any of the components of the preparation.

AvroHB is contra-indicated in cases of anaemias associated with ineffective erythropoiesis, bone marrow hypoplasia and sideroblastic change and in cases of idiopathic or secondary iron storage.

4.4 Special warnings and precautions for use

It is advisable to seek medical advice when possible, particularly for blood examination.

For better bioavailability AvroHB should not be administered concurrently with antacids and neomycin.

4.5 Interaction with other medicinal products and other forms of interaction

Avoid taking concurrently with antacids and neomycin which can reduce absorption of the product.

4.6 Pregnancy and Lactation

No teratogenic effect has been reported with the use of AvroHB Tonic in pregnant women however the normal rule that drugs should be avoided in the first trimester should be borne in mind.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

AvroHB is well tolerated and has no known side effect. When taken in excess amount or above the recommended dosage, gastro-intestinal disturbances such as abdominal cramp, nausea, diarrhoea and vomiting are noticed.

4.9 Overdose

In the case of over dosage, the presenting symptoms are treated symptomatically after gastric lavage or evacuation has been done.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: B05AA10

Haemoglobin

Haemoglobin is the respiratory protein of the red blood cells and consists of 6% heme and 94% globin. It is a tetrameric compound each of the 4 subunits consisting of an iron-photoporphyrin complex containing 1 atom of ferrous iron (haem) in association with a polypeptide (globin). It plays an important role in the organism, transports oxygen from the lungs to the tissues.

Haemoglobin contains about 0.34% of iron. In its oxygenated form it is called oxyhaemoglobin HbO_2 . When the oxygen is displaced by carbon monoxide it is called carboxyhaemoglobin, HbCO_2 . When the iron in haemoglobin is oxidized from the ferrous to the ferric state the compound is called methemoglobin.

Haemoglobin has been used in the treatment of iron-deficiency anemias as a substitute for iron salts.

Therapy should be continued after the haemoglobin concentration has returned to normal, to replenish the body stores of iron.

Vitamin B₁₂ (Cyanocobalamin)

Vitamin B₁₂, water-soluble vitamins occur in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxycobalamin. It act as coenzyme in nucleic acid synthesis.

Vitamin B₁₂ preparations are used in the treatment and prevention of Vitamin B₁₂ deficiency.

Malt Extract

Malt extract contains 50% or more of maltose, with dextrin, dextrose, small amounts of other carbohydrates and protein. It is prepared from malted grain of barley or a mixture of this with not more than 33% of malted grain of wheat.

Malt extract has nutritive properties. It is useful as a flavouring agent.

5.2 Pharmacokinetic properties

Haemoglobin

Haemoglobin contains iron which is irregularly and incompletely absorbed from the gastro-intestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is usually increased in conditions of iron deficiency or when given in the fasting state. Absorption of iron may be reduced in certain disease states.

Apart from haemorrhage, iron is mainly lost from the body in the faeces, urine, skin and sweat, but the total loss is small. In healthy men and non-menstruating women the loss is replaced by the absorption of about 1mg of iron daily; about 2mg needs to be absorbed daily by menstruating women.

Vitamin B₁₂ (Cyanocobalamin)

Vitamin B₁₂ substances bind to intrinsic factor and are then actively absorbed from the gastro intestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy.

Vitamin B₁₂ is extensively bound to specific plasma proteins called Transcobalamins, Transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. It is stored in the liver, excreted

in the bile and undergoes enterohepatic recycling; part of a dose is excreted in the urine, most of it in the first 8 hours. Vitamin B₁₂ diffuses across the placenta and also appears in breast milk.

5.3 Preclinical safety data

No formal preclinical studies have been conducted. However all the individual ingredients are well documented in the literature and the product has been available for many years with no adverse reports recorded.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Liquid Glucose
Propyl Hydroxybenzoate
Methyl Hydroxybenzoate
Malt Flavour
Xanthan Gum
Caramel
96% Ethanol
Deionised Water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

200ml PET bottle with aluminium screw cap.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Applicant/manufacturer

Avro Pharma Limited
Daid House Plot 2, Block J, Limca Way,
Isolo Industrial Estate, Oshodi-Apapa Expressway,
Isolo, Lagos State, Nigeria.
Tel: +234(1)2913955
Email: avro@rumon-org.com