

**MODULE -1**  
**ADMINISTRATIVE AND PRODUCT INFORMATION OF**  
**MIMGLOBIN LIQUID**

**1.3 PRODUCT INFORMATION:**

**1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

**1. Name of the medicinal product:**  
**MIMGLOBIN LIQUID**

**2. Qualitative and Quantitative Composition**

**Composition:**

Each 10 ml contains:

Elemental Iron (as Ferric Ammonium Citrate)	12 mg
Elemental Zinc (as Zinc Sulphate, Heptahydrate B.P.)	7 mg
L - Histidine Hydrochloride Monohydrate B.P.	4 mg
L - Lysine Hydrochloride U.S.P.	50 mg
Thiamine Hydrochloride B.P. (Vitamin B1)	5 mg
Riboflavin B.P. (Vitamin B2) (as Riboflavin Sodium Phosphate B.P.)	1.5 mg
Pyridoxine Hydrochloride B.P. (Vitamin B6)	2.5 mg
Nicotinamide B.P.	25 mg
Dexpanthenol B.P.	2.5 mg
Folic Acid B.P.	500 mcg
Cyanocobalamin B.P. (Vitamin B12)	4 mcg
Flavoured Base	q.s.
Colourant: Caramel	

**3. Pharmaceutical Form:**

Brown coloured sweet viscous liquid with orange flavour.

**4. Clinical Particulars**

**4.1 Therapeutic indications**

Anaemia during Pregnancy & Lactation, Anaemia like Post-Surgical Anaemia. As a supplement in menstruating women, particularly with heavy or prolonged menstrual bleeding.

**4.2 Dosage and Administration:**

Children: 1 (5 ml) or 2 (10 ml) teaspoonful once a day

Adults: 2 (10 ml) or 3 (15 ml) teaspoonful once a day  
or As directed by Physician.

Liquid for oral administration.

**4.3 CONTRA-INDICATIONS :**

**CONTRAINDICATIONS:**

Mimglobin liquid is contra-indicated if the patient is known to be hypersensitive (allergic) to any of the ingredients used in the formulation.

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### 4.4 PREGNANCY AND LACTATION:

Dietary supplementation of amino acids during pregnancy could help in Anemia.

### 4.5 DRUG INTERACTIONS:

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 the absorption of both iron salts and tetracycline is diminished when taken together by mouth. If treatment with both drugs is required, a time interval of about 2 to 3 hours should be allowed between them.

### 4.6 SIDE EFFECTS:

No untoward or serious side effects are expected with the use of Mimglobin liquid. However, some users may experience slight gastro-intestinal intolerance including constipation or mild diarrhoea, nausea, vomiting and abdominal pain. Blackening of faeces may occur with the usage of Mimglobin liquid.

**STORAGE:** Store below 30°C, at a dry place. Protect from light. Keep medicines out of reach of children.

### PRESENTATION:

Pack of 200 ml bottle in a carton.

## 5. Pharmacological properties:

### 5.1 Pharmacodynamic properties

**Vitamin B12** - Vitamin B12 is necessary for normal hematopoiesis (promotes maturation of erythrocytes). It has a beneficial effect on liver function and the nervous system. It also activates the coagulation of blood in high doses and causes an increase in the activity of thromboplastin and prothrombin.

**Zinc**- Zinc is important for immunity against infections. It is needed for the proper growth and maintenance of the human body. It helps speed recovery from the common cold and reduces its symptoms, and eye disease that gradually causes vision loss.

**Iron** - It is an essential constituent of hemoglobin, cytochrome, and other components of respiratory enzyme systems. Its chief functions are in the transport of oxygen to tissue (hemoglobin) and in cellular oxidation mechanisms. Depletion of Iron stores may result in iron deficiency anemia.

**Dexpanthenol:** Pantothenic acid is a precursor of coenzyme A, which serves as a cofactor for a variety of enzyme-catalyzed reactions involving transfer of acetyl groups. The final step in the synthesis of acetylcholine consists of the choline acetylase transfer of acetyl group from acetylcoenzyme A to choline. Acetylcholine is the neurohumoral transmitter in the

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parasympathetic system and as such maintains the normal functions of the intestine. Decrease in acetylcholine content would result in decreased peristalsis and in extreme cases adynamic ileus.

**L-Lysine:** Insures the adequate absorption of calcium; helps form collagen (which makes up bone cartilage & connective tissues); aids in the production of antibodies, hormones & enzymes. Recent studies have shown that Lysine may be effective against herpes by improving the balance of nutrients that reduce viral growth. A deficiency may result in tiredness, inability to concentrate, irritability, bloodshot eyes, retarded growth, hair loss, anemia & reproductive problems.

#### **5.2 Pharmacokinetic properties**

##### **Vitamin B1 (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 B2 (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 B6 (Pyridoxine)**

Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

##### **Vitamin B12 (Cyanocobalamin)**

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 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.

**L-Lysine:** Absorbed from the lumen of the small intestine into the enterocytes by an active transport process

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**6. Pharmaceutical Particulars**

**6.1. List of Excipients**

1. Methylparaben BP
2. Propylparaben BP
3. Benzoic Acid BP
4. Sucrose BP (Crystalline)
5. Sorbitol Solution (70%) BP (Non-Crystallising)
6. Liquid Glucose USP
7. Propylene Glycol BP
8. Xanthan Gum USP/NF
9. Butylated Hydroxyanisole BP
10. Polyethylene Glycol 400 USP-NF
11. Sucralose USP
12. Caramel Type III Grade
13. Sodium Hydroxide BP (Pellets)
14. Sodium Citrate, Dihydrate BP
15. Citric Acid Monohydrate BP
16. Purified Water BP
17. Orange Oil (5 Folds Extract)
18. Honey
19. Malt Extract (Liquid)

**6.2. Incompatibilities:**

Not applicable.

**6.3. Shelf life:**

30 months

**6.4. Special precautions for storage:**

Store below 30°C, at a dry place. Protect from light. Keep medicines out of reach of children.

**6.5. Nature and contents of container:**

Each carton should contain 200ml Mimglobin Liquid filled in a sealed, duly labelled Glass bottle wrapped with a corrugated liner. A Measuring cup is to be fitted on the cap before closing carton. A mixed insert is kept inside the pack above all.

**6.6. Special precautions for disposal and other handling:**

No data available.

**MANUFACTURER**

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