SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Zoglobin Syrup

2. Qualitative and quantitative composition

Each 10ml Contains:

Ferrous glycine Sulphate…… 275mg (Eq. to Elemental iron 47mg)

L-Histidine Hydrochloride H2O BP…….4mg

L-Lysine Hydrochloride USP…….25mg

Thiamine Hydrochloride BP…….5mg

Riboflavin BP (as Riboflavin Sodium Phosphate) BP…….3mg

Pyridoxine Hydrochloride BP……...1.5mg

Folic Acid BP…….0.5mg

Nicotinamide BP…….25mg

Cyanocobalamin BP…….2.5mcg

Dexpanthenol USP…….2.5mg

Colour–Caramel

Excipient(s) with known effects

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Oral liquid.

4. Clinical particulars

4.1 Therapeutic indications

It is prescribed to patients with severe anaemia in the following conditions: anaemia in surgical patients after undergoing surgery, anaemia caused by nutritional deficiencies, anaemia occurring during pregnancy and breastfeeding, and anaemia resulting from heavy menstrual bleeding.

4.2 Posology and method of administration

Posology

2- 6 Years – 2.5 ml Once a day.

7- 12 Years – 2.5 ml twice daily.

12 Year & above– 10 ml twice daily.

Method of Administration

For oral administration.

4.3 Contraindications

- Hypersensitivity to any of its excipients listed in section 6.1. In the event of any adverse reactions, the medication should be discontinued and medical advice should be sought.
- Iron over-load disorder
- Severe renal impairment
- Concomitant use with tetracyclines or levodopa.

4.4 Special warnings and precautions for use

Iron Toxicity: Keep out of the reach of children; overdose may be fatal.
Gastrointestinal effects: May cause constipation, nausea, and dark stools.
Diabetic patients: Contains sucrose; monitor blood glucose.

4.5 Interaction with other medicinal products and other forms of interaction

Potential for amitriptyline to affect other medicinal products

Antacids/PPIs

Reduce iron absorption; administer 2 hours apart.

Tetracyclines/Quinolones

Iron decreases antibiotic absorption.

Levothyroxine

Iron may reduce efficacy; separate administration by 4 hours.

4.6 Fertility, pregnancy and lactation

Pregnancy

Use during pregnancy and lactation is recommended at suggested doses. During pregnancy, the body's demand for all nutrients rises significantly—especially for amino acids and iron. Studies have shown that amino acid requirements can

increase by approximately 65% during pregnancy. The increased need for iron in pregnant women is due to several factors:

- the expansion of maternal blood volume,
- the iron requirements of the growing fetus and placenta, and
- anticipated blood loss during childbirth.

4.7 Effects on ability to drive and use machines

No effect on the ability to drive or use machines

4.8 Undesirable effects

Overdosage may lead to certain adverse effects, including nausea, epigastric pain, changes in bowel habits such as constipation or diarrhoea, vomiting, low blood pressure, and flu-like symptoms. If any of these symptoms occur, discontinue use and consult a physician.

This drug combination is generally recommended to be taken after meals. While food may reduce iron absorption, taking it with meals helps to minimize gastrointestinal side effects like nausea and stomach discomfort.

Reporting of Suspected Adverse Reactions

It is essential to report any suspected adverse reactions following the authorization of this medicinal product. Reporting helps in the continued assessment of the benefit/risk balance of the medication. Healthcare professionals should report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Caution is advised in patients at risk of iron overload, such as those with haemochromatosis, haemolytic anaemia, or red cell aplasia. A lack of response to therapy may suggest alternative causes of anaemia and should prompt further investigation.

This product should not be administered to patients undergoing repeated blood transfusions or those with anaemia unrelated to iron deficiency.

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six years of age. Therefore, this medication must be kept out of reach of children. In cases of overdose, treatment should only be carried out under the supervision of qualified healthcare professionals.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC code: B03AE04 - Iron, Amino Acids and Vitamins.

Iron (Ferrous Glycine Sulfate) is a vital component of hemoglobin, cytochromes, and various respiratory enzyme systems. Its primary roles include transporting oxygen to tissues via hemoglobin and supporting cellular oxidative processes. A deficiency in iron stores can lead to iron-deficiency anaemia. Ferrous Glycine Sulfate is administered to replenish iron levels and treat or prevent iron-deficiency anaemia. Additionally, iron is believed to support immune function, offer potential anticancer properties, and enhance cognitive performance.

Cyanocobalamin (Vitamin B12) is rapidly converted in the body to its active forms, methylcobalamin and deoxyadenosylcobalamin. These coenzymes are essential for converting homocysteine to methionine and methylmalonyl-CoA to succinyl-CoA, respectively—both critical steps for cell growth and replication. Deficiency in Vitamin B12 disrupts these pathways, resulting in megaloblastic anaemia and neurological disorders.

Thiamine (Vitamin B1) deficiency interferes with the hexose monophosphate pathway at the transketolase step, leading to the accumulation of pentose sugars at abnormally high levels.

Riboflavin (Vitamin B2) requirements increase with carbohydrate intake and are elevated during pregnancy, lactation, and in women using oral contraceptives. Long-term use of certain drugs, like phenothiazines, also increases demand. Riboflavin can reduce the antimicrobial effectiveness of antibiotics such as streptomycin, erythromycin, tyrothricin, carbomycin, and tetracycline—particularly through photochemical reactions. It also interacts with other antibiotics like chloramphenicol, penicillin, and neomycin.

Vitamin B6 (Pyridoxine) plays a role in numerous enzymatic reactions involving tryptophan metabolism. In deficiency states, abnormal tryptophan metabolites—especially xanthurenic acid—are excreted in high amounts in urine.

Niacin (Vitamin B3) deficiency leads to pellagra, a disease marked by dermatitis, diarrhoea, dementia, and, if untreated, death. Experimental models have shown that the niacin antagonist 6-aminonicotinamide induces similar pathological effects.

Niacin, in the form of nicotinamide, is essential for forming NAD and NADP coenzymes, which drive tissue redox reactions.

Pantothenol (a form of Vitamin B5) is also essential, though natural deficiencies are rare due to its widespread presence in foods of plant and animal origin.

Folic Acid is critical for normal red blood cell formation. A deficiency can lead to megaloblastic anaemia, glossitis, and unintended weight loss.

Histidine HCl and Lysine HCl are essential amino acids, particularly important during infancy and growth. A deficiency may cause conditions such as histidinaemia and hypochloraemic alkalosis.

5.2 Pharmacokinetic properties

Ferrous Glycine Sulphate is absorbed in the ferrous form through the gastrointestinal tract. In healthy individuals, absorption is relatively low—around 10%. However, in patients with iron-deficiency anaemia, absorption can increase significantly, reaching up to 60% of the administered dose. Once absorbed, iron binds to transferrin and is transported to the bone marrow for incorporation into haemoglobin. Iron released from the breakdown of haemoglobin is efficiently recycled and reused by the body.

Cyanocobalamin (Vitamin B12) is absorbed from the gastrointestinal tract, although absorption can be inconsistent at high therapeutic doses. It is notably reduced in individuals lacking intrinsic factor, those with gastrointestinal disorders, malabsorption syndromes, or following gastrectomy. Normally, only about 1.5 to 3.5 ng of cyanocobalamin can be absorbed per meal via intrinsic factor-mediated pathways, but roughly 1% of an oral dose can also be absorbed via passive diffusion. After absorption, it binds to plasma proteins and is primarily stored in the liver. When administered in doses of 100 µg or more, over half is excreted in the urine within 48 hours, most within the first 8 hours.

Pyridoxine (Vitamin B6) is absorbed through the gastrointestinal tract and converted into its active form, pyridoxal phosphate. Other forms such as pyridoxal and pyridoxamine are also absorbed and transformed. The primary route of excretion is via the urine, mainly as 4-pyridoxic acid.

Riboflavin (Vitamin B2) is absorbed from the gastrointestinal tract and circulates in the blood bound to plasma proteins. Small amounts are stored in organs like the liver and kidneys, while excess amounts are excreted in the urine.

Thiamine (Vitamin B1) is also absorbed from the gastrointestinal tract and distributed throughout body tissues. It is not significantly stored in the body, and excess is excreted in the urine either as unchanged thiamine or as its metabolite, pyrimidine. The human body metabolizes about 1 mg of thiamine daily.

Nicotinamide (Vitamin B3) is efficiently absorbed from the gastrointestinal tract and is widely distributed in body tissues. It is excreted in the urine as methylated and oxidized metabolites.

Folic Acid is primarily absorbed from the proximal small intestine. During absorption, folate polyglutamates are deconjugated into monoglutamate forms. After absorption, folic acid appears rapidly in the bloodstream, where it binds extensively to plasma proteins. It is distributed to various tissues, partially stored in the liver, and excess amounts are excreted in the urine.

Histidine is absorbed in the small intestine via an active transport mechanism that requires sodium.

Lysine, like other amino acids, is absorbed and then either used for protein synthesis or undergoes oxidative catabolism. It plays a critical role in the biosynthesis of compounds like carnitine, collagen, and elastin.

5.3 Preclinical safety data

Not available.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose
Liquid Glucose
Glycerin
Bronopol
Sorbitol 70 % Solution
Propylene Glycol
DiSodium EDTA
Sodium Citrate
Tromethamine Buffer
Sodium Hydroxide

Citric Acid monohydrate
Colour Caramel
Purified water.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years

6.4 Special precautions for storage
Store below 30°C. Protect from Light. Keep out of the reach of Children.

6.5 Nature and contents of container
Zoglobin Syrup is filled in a 200ml Amber coloured brute shaped glass bottle. Each bottle is packed in a mono carton along with insert.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorisation holder
GLPL Limited

India

8. Marketing authorisation number(s)
N/A

9. Date of first authorisation/renewal of the authorisation
N/A

10. Date of revision of the text
N/A