

Summary of Product Characteristics

G-AMINO SYRUP

1. Name of the medicinal product

G-AMINO syrup

2. Composition

Each 5 ml contains:

Ferrous glycine Sulphate	275 mg
L-Histidine Hydrochloride H ₂ O BP	4 mg
L-Lysine Hydrochloride BP	25 mg
Thiamine Hydrochloride BP	5 mg
Riboflavin BP	
(as Riboflavin Sodium Phosphate)	3 mg
Pyridoxine Hydrochloride BP	1.5 mg
Folic Acid BP	0.5 mg
Nicotinamide BP	25 mg
Cyanocobalamin BP	2.5 mcg
Dexpanthenol USP	2.5 mg
Colour –Caramel	

3. Pharmaceutical form

Oral liquid

4. Clinical particulars

4.1 Therapeutic indications

G-Amino Syrup is prescribed to severely anaemic patients in the following conditions :

- Anaemia in surgical patients following surgery
- Anaemia due to nutritional deficiencies
- Pregnancy and Lactation
- Anaemia due to heavy bleeding during menstruation

4.2 Posology and method of administration

Route of administration: oral.

Dosage and administration:

2 - 6 Years - 1.25 ml Once a day.

7 - 12 Years 1.25 ml twice daily.

12 Year & above – 5 ml twice daily.

4.3 Contraindications

G-Amino Syrup is well tolerated and can be safely prescribed to all age group. It has no known contraindications. Mild GI disturbance rarely noticed.

G-Amino Syrup may be contraindicated in patients with hypersensitivity to any of the ingredients of the product. If any side effect is noticed discontinue the medication and consult doctor.

4.4 Special warnings and precautions for use

Before using G-Amino Syrup, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens.

4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of G-Amino 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. G-Amino Syrup may interact with the following drugs and products:

- Antacids
- Bisphosphonate
- Calcium supplements

- Levodopa
- Methyldopa
- Penicillamine
- Quinolones
- Tetracycline

4.6 Pregnancy and lactation

It is safe to use G-Amino during Pregnancy and Lactation in indications suggested at recommended doses.

In pregnancy, the body need of all nutrients increase and more so for Amino acids and Iron. In fact studies show that there is an estimated 65% increase in the body's needs for Amino acid during pregnancy.

In Pregnant Women there is an increased need for iron due to:

- * Expanded blood volume in the mother
- * Foetal and placental requirements
- * Blood loss during delivery

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Certain adverse reactions may be produced due to over dosage of G-Amino Syrup are nausea, epigastric pain, altered bowel habit - constipation or diarrhoea, vomiting, hypotension and flu-like symptoms. If these reactions are noticed discontinue the medication and consult doctor. These drug combination should generally be prescribed after meals; although taking iron with a meal reduces absorption, it lessens GI side-effects, such as nausea and epigastric discomfort.

4.9 Overdose

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. It should not be given to patients receiving repeated blood transfusion or with anaemia not produced by iron deficiency.

Accidental overdose of an iron-containing product is a leading cause of fatal poisoning in children less than 6 years. Keep this product out of reach of children. During the overdose, the treatments must be done only under expert supervision.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

Iron (Ferrous Glycine Sulfate) 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. Iron (Ferrous Glycine Sulfate) is used to build up the blood in anemia.

The major activity of supplemental Iron (Ferrous Glycine Sulfate) is in the prevention and treatment of Iron deficiency anemia. Iron has putative immune-enhancing, anticarcinogenic and cognition-enhancing activities.

Cyanocobalamin is readily converted into the coenzyme forms which as methylcobalamin, is converted with conversion of homocysteine to methionine, and, as deoxyadenosylcobalamin in conversion of methylmalonyl – CoA to Succinyl – CoA. The active coenzymes, enzymes, methyl – cobalamin and 5 – deoxyadenosylcobalamin, are essential for cell growth and replication. In man, failure of this pathway due to cobalamin deficiency leads to a megaloblastic anaemia and to a neuropathy.

In Thiamine deficiency, the hexose monophosphate pathway of glucose oxidation is retarded at the level of the transketolase, So pentose sugars accumulate to levels three times the normal.

The requirement for Riboflavin depends on the carbohydrate intake and is increased during pregnancy, lactation and in woman taking oral contraceptive agents. Riboflavin requirement is also increased by prolonged administration of drugs such as phenothiazines. Riboflavin reduces the antibacterial activity of solutions of streptomycin, erythromycin, tyrothricin, carbomycin and tetracycline, in the case of tetracyclines, the reaction is a photochemical oxidation. Inactivation also occurs with chloramphenicol, penicillin or neomycin.

In the metabolism of tryptophan, Vitamin B₆ is involved in a number of enzymatic reactions. In Vitamin B₆ - deficient humans and animals, a number of metabolites of tryptophan, especially xanthurenic acid, are excreted in urine in abnormally large quantities. Chronic dietary deficiency of niacin results in the disorder pellagra, which is characterized by dermatitis, diarrhoea, dementia and ultimately death. Administration of the antimetabolite, 6-aminonicotinamide, to mice produced pathologic lesions of the skin, intestine, and central nervous that were characteristic of those described in human pellagra. Nicotinamide is needed for the co enzymes NAD and NADP that catalyse tissue oxidation- reduction reactions.

Pantothenol is an essential nutrient. However, naturally occurring deficiency has rarely been observed, probably because of its ubiquity in plant and animal tissues.

Folic Acid is necessary for the normal production of red blood cells, Deficiencies may cause Megaloblastic anaemia, Glossitis & Loss of weight.

Histidine HCl & Lysine HCl are essential amino acid for infants & growing children. Deficiencies of these amino acid causes diseases with histidinanaemia, Hypochloraemic Alkalosis.

5.2 Pharmacokinetic properties

Ferrous Glycine Sulphate absorbed orally in ferrous form and poorly absorbed in healthy individuals (about 10%) but in patients suffering from iron deficiency anaemia up to 60% dose is absorbed. Transported in a transferrin bound form in to bone marrow for incorporation in to haemoglobin. Iron liberated by destruction of haemoglobin is reused by the body.

Cyanacolobalamin is absorbed from the gastro-intestinal tract, but it may be irregularly absorbed when given in large therapeutic doses and 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. Only 1.5 to 3.5 ng can be absorbed from any one meal by the process involving intrinsic factor but about 1% of the amount given by mouth is also absorbed by passive diffusion. Cyanacolobalamin is bound to plasma proteins and is stored in liver. When given in doses of 100 µg or more, more than one-half is excreted in the urine within 48 hours, most of it in the first 8 hours.

Pyridoxine is absorbed from the gastrointestinal tract and is converted to the active form pyridoxal phosphate. Pyridoxal and pyridoxamine are also absorbed and converted. It is excreted in the urine as 4-pyridoxic acid.

Riboflavin is absorbed from the gastrointestinal tract, and in the circulation it is bound to plasma proteins. A little is stored in organs such as the liver and kidneys, and amounts in excess of the body's requirements are excreted in the urine.

Thiamine is absorbed from the gastrointestinal tract and is widely distributed to most tissues. It is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine as unchanged thiamine or as its metabolite, pyrimidine. About 1 mg of thiamine is metabolized in the body daily.

Pyridoxine is absorbed from the gastrointestinal tract and is converted to the active form pyridoxal phosphate. Pyridoxal and pyridoxamine are also absorbed and converted. It is excreted in the urine as 4-pyridoxic acid.

Nicotinamide is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Methylated and oxidized metabolites are excreted in the urine.

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.

Histidine is absorbed from the small intestine via an active transport mechanism requiring the presence of sodium and like other amino acids, the metabolism of free Lysine follows two principal paths: protein synthesis and oxidative catabolism. It is required for biosynthesis of such substances as carnitine, collage, 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, Di-Sodium EDTA, Sodium Citrate, Tromethamine Buffer, Sodium Hydroxide, Citric Acid monohydrate, Colour Caramel, Fla. Pineapple Sweet , Fla. Peppermint Troomint, Purified water.

6.2 Incompatibilities

Not known

6.3 Shelf life

2 years (24 months)

6.4 Special precautions for storage

Preserve in well-closed, light-resistant containers. Store below 30°C

Keep out of reach of children.

Shake well before use.

6.5 Nature and contents of container

G-Amino syrup is filled in a 200 ml 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

BLISS GVS PHARMA LTD.

102, Hyde Park,

Saki Vihar Road, Andheri (East),

Mumbai – 400 072, INDIA

Tel. : (+91) (22) 42160000 / 28505387

Fax : (+91) (22) 28563930

E-mail : info@blissgvs.com