Legal Category

POM: Over The Counter

SmPC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

KRISTYFER Syrup

Iron, Amino Acids & Vitamins Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml (one tablespoonful) contains:

Ferrous Glycine Sulphate……..…….275mg

(Equivalent to Elemental iron 47mg)

L-Histidine Hydrochloride BP……..4mg

L-Lysine Hydrochloride USP…….25mg

Thiamine Hydrochloride BP…….5mg

Riboflavin BP……3mg

Pyridoxine Hydrochloride BP……1.5mg

Folic acid BP……..0.5mg

Nicotinamide BP ……25mg

Cyanocobalamin BP…….2.5mcg

Dexpanthenol USP…….2.5mg

Overages of Vitamins added to compensate loss on storage

3. PHARMACEUTICAL FORM

Oral Liquid

Light Brown colored Chocolate flavored syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

KRISTYFER Syrup is indicated for

- Iron deficiency anaemia due to chronic blood loss, hook-worm infestation, inadequate intake of iron, etc.
- Dimorphic anaemia 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.

Posology and method of administration

Shake well before to each use

Adults: For Adults: (For Therapeutic use) 1 tablespoonful (15ml) twice a day after meals.

Children: As advised by the Physician.

Method of Administration

oral

4.2 Contraindications

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

4.3 Special warnings and precautions for use

- Iron compounds should not be given to patients receiving repeated blood transfusions or to patients with anemia not produced by iron deficiency unless iron deficiency is also present.
- 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.
- Liquid preparations of iron salts should be swallowed through a straw to prevent discoloration of the teeth.

4.4 Interaction with other medicinal products and other forms of interaction

- 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 at least 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.

4.5 Pregnancy and lactation

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

4.6 Effects on ability to drive and use machines

KRISTYFER SYRUP has no influence on the ability to drive or use machines.

4.7 Undesirable effects

Ferrous Glycine Sulphate:

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.

4.8 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

Pharmacotherapeutics group: Kristyfer syrup

5.1 Pharmacodynamic properties

Ferrous Glycine Sulphate:

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

Iron is necessary for the production of hemoglobin. Iron-deficiency can lead to decreased production of hemoglobin and a microcytic, hypochromic anemia.

L-Histidine Hydrochloride:

Histidine is an essential amino acid. It is not made by the body, but is consumed in foods. Amino acids are the building blocks of protein. Histidine is involved in many different metabolic processes in the body. People use histidine for diarrhea due to cholera infection, eczema, kidney failure, metabolic syndrome, and many other conditions, but there is no good scientific evidence to support these uses.

L-Lysine hydrochloride:

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.

Thiamine:

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro- intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

Riboflavin:

Riboflavin is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide which act as co-enzymes in the respiratory chain and in oxidative phosphorylation. Riboflavin deficiency presents with ocular symptoms, as well as lesions on the lips and at angles of the mouth.

Pyridoxine:

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine. B-complex Vitamin The vitamin B-complex comprises a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin of the B-complex forms part of a co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

Folic acid:

Folic acid is a water-soluble B-complex vitamin found in foods such as liver, kidney, yeast, and leafy, green vegetables. Also known as folate or Vitamin B9, folic acid is an essential cofactor for enzymes involved in DNA and RNA synthesis. More specifically, folic acid is required by the body for the synthesis of purines, pyrimidines, and methionine before incorporation into DNA or protein. Folic acid is the precursor of tetrahydro folic acid, which is involved as a cofactor for transformation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Impairment of thymidylate synthesis in patients with folic acid deficiency is thought to account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic and macrocytic anemias. Folic acid is particularly important during phases of rapid cell division, such as infancy, pregnancy, and erythropoiesis, and plays a protective factor in the development of cancer. As humans are unable to synthesize folic acid endogenously, diet and supplementation is necessary to prevent deficiencies. In order to function properly within the body, folic acid must first be reduced by the enzyme dihydrofolate reductase (DHFR) into the cofactors dihydrofolate (DHF) and tetrahydrofolate (THF). This important pathway, which is

required for de novo synthesis of nucleic acids and amino acids, is disrupted by anti-metabolite therapies such as Methotrexate as they function as DHFR inhibitors to prevent DNA synthesis in rapidly dividing cells, and therefore prevent the formation of DHF and THF.

Nicotinamide:
The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adenine dinucleotide phosphate) include the degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency produces pellagra and mental neurological changes.

Cyanocobalamin:
Vitamin B12 is present in the body mainly as methyl cobalamin and as adenosyl cobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerization of methyl malonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with hemopoiesis and produces megaloblastic anaemia.

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 acetyl coenzyme A to choline. Acetylcholine is the neurohumoral transmitter in the 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.

5.2 Pharmacokinetic properties:

Ferrous Glycine Sulphate:

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

L-Histidine Hydrochloride:

L- Histidine Hydrochloride is absorbed from the gastro-intestinal tract and is widely distributed in plasma proteins, as carnosine in skeletal muscles and in haemoglobin.

The small intestine is the primary site of amino acid and glucose absorption into the blood. These solutes are transported by three processes: simple diffusion, facilitated diffusion, and "active" transport.

L-Lysine hydrochloride:

Oral administration is the preferred route for lysine supplementation. Upon ingestion, it is absorbed from the lumen of the small intestine into the enterocytes via active transport and moves from the gut to the liver via the portal circulation.

Thiamine HCl

Thiamine HCl 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.

Riboflavin:

Riboflavin 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 riboflavin is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

Pyridoxine HCl:

Pyridoxine HCl 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.

Folic acid:

Well absorbed from the GI tract. Synthetic folic acid is almost 100% bioavailable following oral administration in fasting individuals; folate in food is about 50% bioavailable. Synthetic folic acid is 85–100% bioavailable following oral administration with a meal. Distributed into all body tissues including the CNS; stored mainly in the liver. Distributed into all body tissues including the CNS; stored mainly in the liver. Up to 90% of a dose in urine; small amounts in feces.

Nicotinamide: Nicotinic acid is absorbed from the gastro-intestinal tract, is widely distributed in the body tissues and has a short half-life.

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.

Dexpanthenol:

Dexpanthenol is is absorbed from the gastro-intestinal tract and readily converted to pantothenic acid which is widely distributed into body tissues, mainly as coenzyme A. Highest concentrations are found in the liver, adrenal glands, heart, and kidneys.

5.3 Pre-clinical Safety:

None Stated.

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Sorbitol, Sodium Methyl Paraben, Sodium Propyl Paraben, Saccharin sodium, Chocolate Flavor, Propylene Glycol, Caramel color, Purified water

6.2 Incompatibilities:

There are no significant incompatibilities with the product.

6.3 Shelf Life

3 Years.

6.4 Special Precautions for storage

Store in a cool, dark and dry place, below 30°C in a dry place.

6.4 Nature and contents of container

200 amber PET bottle provided with a measuring cup packed in a Carton along with the Pack Insert.

6.5 Special precautions for disposal and other handling

No Special requirement for disposal

7. Marketing Authorization Holder:

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State, NIGERIA.

Email: info@krishatpharma.com

8. Marketing Authorization Number (s)

NA

9. Date of first Authorization /renewal of the authorization

NA

10. Date of revision of text

NA

Company contacts details

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