LAFIARON® BLOOD CAPSULES.

(IRON, VITAMIN B_{12}, FOLIC ACID AND VITAMIN C)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC) .

1 NAME OF THE MEDICINAL PRODUCT:

Lafiaron Blood Capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Ferric Ammonium Citrate B.P…….....80mg
Vitamin B_{12} (Cyanocobalamin) B.P ……5mcg
Folic acid B.P…….500mcg
Vitamin C B.P……25mg
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral capsule

4 CLINICAL PARTICULARS

Lafiaron Blood Capsule is indicated in iron deficiency anaemia caused by trauma, surgery from hookworm infestation, child delivery, menstruation and dietary deficiency; in situations of increased iron demand as in pregnancy, lactation as well as in growing children and for the elderly with the problem of poor iron ingestion or absorption. It is also indicated in convalescence from prolonged and debilitating illness with symptoms such as weakness, lack of concentration, lassitude, pallor and tiredness; anaemia due to febrile illness like malaria, typhoid and influenza.

4.1 Therapeutic indications

Iron is most commonly used for preventing and treating anemia caused by low iron levels. It is also used for anemia caused by abnormal heavy bleeding during menstrual periods (menorrhagia), pregnancy, or kidney problems.
Iron helps red blood cells carry oxygen from the lungs to cells all over the body. Iron also plays a role in many important functions in the body.
Vitamin B12 is most commonly used for vitamin B12 deficiency, a condition in which vitamin B12 levels in the blood are too low, as well as cyanide poisoning and high levels of homocysteine in the blood (hyperhomocysteinemia).
Vitamin B12 is required for the proper function and development of the brain, nerves, blood cells, and many other parts of the body.
Folic acid is indicated for the treatment of megaloblastic anaemia due to folic acid deficiency. It is also used for prophylaxis in chronic haemolytic states, in renal dialysis, and in drug induced folate deficiency.
Folic acid is used for the prevention of recurrence of neural tube defects
Vitamin C is indicated for the treatment of vitamin C deficiency (e.g. scurvy) and associated symptoms (e.g. temporary tiredness) in adults and adolescents aged 15 years and older.

4.2 Posology and method of administration
For oral administration.

Dosage: Adult and children over 12 years

4.3 Contraindications
Lafiaron Blood Capsules should not be given to patients receiving repeated blood transfusions and should not be administered concomitantly with parenteral iron.

4.4 Special warnings and precautions for use
1.Lafiaron Blood Capsule contains ferric ammonium citrate which may stain teeth and also cause discoloration of stool.
2. The stated dose should not be exceeded
3. No other medicine containing iron should be taken without prior medical consultation
4. This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products
Aspirin can lower plasma levels of vitamin C (a component of the Lafiaron Blood Capsules) by increasing its urinary excretion.
Medicinal products that contain oestrogen, such as oral contraceptives (birth control pills) and hormone replacement therapy, can lower plasma concentrations of vitamin C.
Calcitonin increases the rate of vitamin C excretion.
Barbiturates (phenobarbital) may increase vitamin C excretion in the urine.
At high doses (>1 g/day), vitamin C can decrease the effect of anticoagulants. More frequent monitoring of the INR and a possible dosage adjustment are recommended.
A reduction in indinavir blood levels has been reported following administration of high doses of vitamin C. This should be taken into account in patients being treated with protease inhibitors.
High doses of vitamin C taken together with iron may cause an iron overload due to an enhanced iron reabsorption.
High doses of vitamin C may decrease the urinary excretion of paracetamol, which could increase paracetamol blood levels.
Vitamin C may impair the bioavailability of cyclosporine A, phenothiazines and warfarin, and therefore, may decrease the therapeutic effect of these medicinal products.
Prolonged use of high doses of vitamin C can influence the interaction between disulfiram and alcohol.

4.6 Pregnancy and lactation
The IOM recommends multivitamins that contain iron, zinc, copper, calcium, folic acid, and vitamins D, C, B6, and B12 (note that iodine is not included) for some groups of pregnant women, such as those with iron-deficiency anemia or poor-quality diets, vegetarians, cigarette smokers, and those who consume alcohol.

Folic acid is a B vitamin that every cell in your body needs for healthy growth and development. Taking folic acid before and during early pregnancy can help prevent birth defects of the brain and spine called neural tube defects

- Most mineral supplements (e.g., iron, calcium, copper, chromium, zinc) taken by the mother do not affect breastmilk levels.
- Water soluble vitamin supplements (e.g., B vitamins, vitamin C) taken by the mother usually increase breastmilk levels. Breastmilk levels of some water soluble vitamins, such as vitamin C, only increase up to a certain point, then remain steady – even if mom increases her dose.

4.7 Effects on ability to drive and use machines
None expected at recommended doses and duration of therapy.

4.8 Undesirable effects
Lafiaron Blood Capsule is usually well-tolerated. However, there may be a few cases of gastrointestinal upsets due to iron intolerance. This may be minimized by reducing the dosage and also by administering after meals.

4.9 Overdose
If overdose is suspected, your doctor should be contacted immediately. In acute poisoning, wash out the stomach with 1% sodium bicarbonate solution and then 5 to 10g of Desferrioxamin Masylate in 50 to 100ml of water by mouth, or by stomach tube to chelate any iron left in the stomach immediately by emesis and lavage using 1 to 5% solution of sodium bicarbonate, and leave up to about 300ml of the solution in the stomach.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
ATC code: BO3AE04

Mechanism of action:

Iron combines with porphyrin and globin chains to form hemoglobin, which is critical for oxygen delivery from the lungs to other tissues.

Vitamin B12 is a coenzyme involved in the metabolism of every cell of the human body, especially affecting DNA synthesis and regulation, but also fatty acid metabolism and amino acid metabolism

Folic acid (Vitamin B9) is a precursor needed to make, repair, and methylate DNA; a cofactor in various reactions; especially important in aiding rapid cell division and growth, such as in infancy and pregnancy.

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 tetrahydrofolic acid, which is involved as a cofactor for transformylation 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.

Ascorbic acid (vitamin C) is essential to humans. Its components, ascorbic acid and dehydroascorbic acid, form an important redox system. Ascorbic acid has special functions in this redox interrelationship, as an antioxidant and enzyme cofactor, which plays a crucial role in various hydroxylation reactions. There are several ascorbate- dependent mono- and dioxygenations in various neurotransmitter and hormone formation processes, and ascorbate is also required for the hydroxylation of carnitine. It has been suggested that carnitine deficiency is responsible for the early symptoms of scurvy. Vitamin C has certain biological functions that can influence energy production and thus physical performance. In addition to its role for synthesis of collagen and carnitine, which transports long-chain fatty acids into mitochondria.

Ascorbic acid facilitates the transport and uptake of non-heme iron at the mucosa, the reduction of folic acid intermediates, and the synthesis of cortisol. Vitamin C is a potent antioxidant that serves to regenerate vitamin E from its oxidized product.

5.2 Pharmacokinetic properties
Absorption of iron from the gut is carefully regulated. Because there is no active excretory process for iron once it has entered the bloodstream, the body's control of iron levels is undertaken at the level of the enterocyte.

Vitamin B_{12} substances bind to intrinsic factor; glycoproteins secreted by the gastric mucosa and are then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor.

Folic acid is absorbed rapidly from the small intestine, primarily from the proximal portion. Naturally occurring conjugated folates are reduced enzymatically to folic acid in the gastrointestinal tract prior to absorption. Folic acid appears in the plasma approximately 15 to 30 minutes after an oral dose; peak levels are generally reached within 1 hour.

Ascorbic acid (Vitamin C) is rapidly absorbed by sodium-dependent active transport from the intestine, although the proportion absorbed decrease with increasing doses.
It is present in plasma and is extensively distributed to all cells of the body, with higher levels found in the adrenal glands, pituitary and retina, and lower levels in kidney and muscle tissue. Tissue vitamin C concentrations are higher than that of plasma but saturate before.
Ascorbic acid is readily oxidized to dehydroascorbic acid. Irreversible breakdown yields 2,3-diketogulonic acid (without biological action), which is then oxidised to oxalic and threonic acids.
The main route of excretion of ascorbic acid is in urine, but a small percentage is excreted in the faeces. Absorbed excess doses are largely excreted unchanged in urine. The plasma half-life of ascorbic acid in humans is 16 days.
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5.3 Preclinical safety data
None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Talc Powder, Magnesium Stearate, Methyl Paraben, Propyl Paraben

6.2 Incompatibilities
None stated except as in 'Interactions with other medicaments.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C.

Keep away from light

6.5 Nature and contents of container
10 capsules blistered in aluminlum foil and PVC.

6.6 Special precautions for disposal and other handling
None

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

N/A

9. Date of first authorisation/renewal of the authorization

N/A

10. Date of revision of the text

N/A