REVENTIN® BLOOD TONIC

(IRON + B-COMPLEX + MULTI MINERALS TONIC)

SUBMITTED BY: XENTIAL PHARMACEUTICALS NIGERIA LTD.

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1 NAME OF THE MEDICINAL PRODUCT:

Reventin Blood Tonic

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Ferric Ammonium Citrate (eq. to 17 mg Iron) B.P……...85 mg
Folic Acid B.P……...250 mcg
Vit. B_{12} B.P……..5 mcg
Vit. B_1 B.P……..2 mg
Vit. B_2 (Riboflavin Phosphate) B.P……2 mg
Vit. B_6 B.P……..2 mg
Zinc (as Sulphate) B.P……5 mg
Copper B.P……0.4 mg
Nicotinamide BP……..5 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Reventin Blood Tonic 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.. It is also used to treat vitamin or mineral deficiencies caused by illness, pregnancy, poor nutrition, digestive disorders, certain medications, and many other conditions.

4.2 Posology and method of administration
For oral administration.

Dosage:
Adult: 5 - 10 ml three times daily or as directed by the physician.
Children: 5 ml three times a day or as directed by physician.

4.3 Contraindications
Reventin Blood Tonic is contraindicated in patients with hypersensitivity to any of the active components of this drug.

4.4 Special warnings and precautions for use

1. Reventin Blood Tonic 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
Pyridoxine hydrochloride, a component of Reventin Blood Tonic may reduce the effectiveness of levodopa.

Many drugs are known to interact with multivitamins and minerals. The interactions are classified into
- major drug interactions
- moderate drug interactions
- minor drug interaction.

Consult your physician or Pharmacist before combining multivitamins with other drugs.

4.6 Pregnancy and lactation
The IOM recommends multivitamins that contain iron, zinc, copper, folic acid, B6, B12 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 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, copper, zinc) taken by the mother do not affect breastmilk levels.
Water soluble vitamin supplements (e.g., B vitamins) taken by the mother usually increase breastmilk levels.

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

4.8 Undesirable effects
Reventin Blood Tonic is usually well-tolerated. However, there may be a few cases of upset stomach and headache.

4.9 Overdose
Overdose symptoms may include stomach pain, vomiting, diarrhea, constipation, loss of appetite, hair loss, peeling skin, tingly feeling in or around your mouth, changes in menstrual periods, weight loss, severe headache, muscle or joint pain, severe back pain, blood in your urine, pale skin, and easy bruising or bleeding.

If overdose is suspected, your doctor should be contacted immediately.

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.

Vitamins and minerals are considered essential nutrients—because acting in concert, they perform hundreds of roles in the body. They help shore up bones, heal wounds, and bolster your immune system. They also convert food into energy, and repair cellular damage.
Vitamin B_1 is essential for proper carbohydrate metabolism and plays an essential role in the decarboxylation of alpha keto acids
Riboflavin is essential for the utilisation of energy from food. It is a component of co-enzymes which play an essential role in oxidative/ reductive metabolic reactions. Riboflavin is also necessary for the functioning of pyridoxine and nicotinic acid.
Nicotinamide is an essential component of co-enzymes responsible for proper tissue respiration.
Vitamin B_6 is a constituent of the co-enzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play an important role in protein metabolism.
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.
Vitamin B_{12} 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
Zinc is component of many metalloenzymes.example: red blood cell carbonic anhydrase, alkaline phosphatase ,alcohol dehydrogenase, carboxy-peptidase, SOD (cytosol), and many enzymes involved in RNA and DNA synthesis, such as DNA and RNA polymerases.
Copper is absorbed from the gut via high affinity copper uptake protein and likely through low affinity copper uptake protein and natural resistance-associated macrophage protein-2 [4]. It is believed that copper is reduced to the Cu1+ form prior to transport. Once inside the enterocyte, it is bound to copper transport protein ATOX1 which shuttles the ion to copper transporting ATPase-1 on the golgi membrane which take up copper into the golgi apparatus. Once copper has been secreted by enterocytes into the systemic circulation it remain largely bound by ceruloplasmin (65-90%), albumin (18%), and alpha 2-macroglobulin (12%).

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.

All the B Vitamins are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

Small amounts of thiamine are well absorbed from the gastrointestinal tract after oral doses, but the absorption of doses larger than about 5mg is limited. Thiamine is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine unchanged or as metabolites.
Riboflavin is readily absorbed from the gastrointestinal tract. Although riboflavin is widely distributed to body tissues little is stored in the body.
Riboflavin also crosses the placenta and is distributed into breast milk. It is widely distributed to most body tissues and appears in breast milk.
Riboflavin is excreted in urine, partly as metabolites.
Pyridoxine B_6 (pyridoxal and pyridoxamine) are readily absorbed from the gastrointestinal tract after oral doses and are converted to the active forms pyridoxal phosphate and pyridoxamine phosphate.
Pyridoxine is stored mainly in the liver where there is oxidation to 4-pyridoxic acid. Pyridoxal crosses the placenta and is distributed into breast milk.
As the dose increases, proportionally greater amounts are excreted unchanged in the urine.
Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductase. It is converted to the metabolically active form 5 methltetrahydrofolate in the plasma and liver.
The principal storage site of folate is the liver; it is also actively concentrated in the cerebrospinal fluid. Folate undergoes enterohepatic circulation.
Folate is distributed into breast milk. Folic acid is removed haemodialysis.
Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine.
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.
Vitamin B_{12} is stored in the liver, excreted in the bile and most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B_{12} diffuses across the placenta and also appears in breast milk.
Vitamin B_{12} undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine.
Absorption of zinc from the gastrointestinal tract is incomplete and is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 to 30%.
Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, eye and prostatic fluids. It is primarily excreted in the faeces and regulation of faecal losses is important in zinc homoeostasis. Small amounts are lost in urine and perspiration.
Copper absorption varies inversely with intake. Absorption range is 12-65%. Copper appears to be eliminated primarily through bile.

5.3 Preclinical safety data
None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium CMC, Sorbitol, Methyl Paraben, Propyl Paraben, Glycerin, Xanthan Gum, Sugar, Strawberry Flavour, Caramel Colour, Sodium Benzoate, Treated Water

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
200ml HDPE amber pet bottle, 28mm ROPP caps

6.6 Special precautions for disposal and other handling
None

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

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8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S)

Not available