TUYIL PHARMACEUTICAL INDUSTRIES LIMITED

NO 22, NEW YIDI ROAD ILORIN, KWARA STATE NIGERIA

SUMMARY OF PRODUCT CHARACTERISTICS[SmPC]

1.0 NAME OF THE MEDICINAL PRODUCT

Bunto Blood Tonic

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingrident: Each 5ml contains

Ferric Ammonium Citrate (85.00mg equivalent to 17mg iron), Folic Acid (250mcg), Vitamin B_{12} (5.00mcg), Vitamin B_1 (2.00mg), Vitamin B_6 (2.00mg), Vitamin B_2 (2.00mg), Nicotinamide (5.00mg), Zinc Sulphate (5.00mg) and Copper Sulphate (0.40mg)

List of Excipients

Granulated Sugar (2500.00mg), Methylparaben (10.00mg) and Propylparaben (1.00mg), Citric Acid (5.00mg), Pineapple Flavour (0.0075mg) and Liquid Glucose (1500.00mg).

3.0 PHARMACEUTICAL FORM

A dark brown syrup with a characteristic odour in an amber bottle

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Multivitamin Syrup is indicated for the prevention of vitamin deficiencies and for the maintenance of normal growth and health during the early years of infancy and childhood.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Dosage

Adult: 10ml (2 teaspoonful) to be taken three times daily

Prophylactic dose: 5ml (1 teaspoonful) once or twice daily

Children: 5ml (1 teaspoonful) once or twice daily or as directed by the physician.

Method of Administration

Oral administration

4.3 Contraindications

Bunto Blood Tonic must not be used in:

- hypersensitivity to the active substances, especially vitamin B1 or to any of the excipients listed above

- hypervitaminosis from any vitamin contained in this formulation,

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Multivitamins are not recommended for the treatment of severe specific deficiencies of vitamins and minerals. While taking the multivitamins, both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision. Do not take on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Interactions between specific vitamins in Bunto Blood Tonic and other agents should be managed accordingly. Such interactions include:

• Alcohol (chronic excessive consumption): Increases the risk of vitamin A hepatotoxicity

• Certain anticonvulsants (e.g., phenytoin, carbamazepine, phenobarbital, valproate): Can cause folate, pyridoxine deficiencies

• Chloramphenicol: Can inhibit the hematological response to vitamin B_{12} therapy

• Ethionamide: Can cause pyridoxine deficiency

• Levodopa: The content of pyridoxine may interfere with the effects of concurrent levodopa therapy.

• Pyridoxine antagonists, including cycloserine, hydralazine, isoniazid, penicillamine, phenelzine: Can cause pyridoxine deficiency

• Theophylline: Can cause Vitamin B_6 deficiency

4.6 Fertility, pregnancy and lactation

Bunto Blood Tonic may be administered during pregnancy and lactation

at the recommendation of the physician.

4.7 Effects on ability to drive and use machines

There is no information on the effects of Bunto Blood Tonic on the ability to operate an automobile or other heavy machinery.

4.8 ADVERSE REACTIONS

Generally multivitamin and multimineral are well tolerated by the body. Sometimes, reactions could occur, but they disappear rapidly after continuous and regular use.

Nicotinamide, VitaminB_6, VitaminB_2 and VitaminB_1 These water-soluble vitamins are generally nontoxic compounds with a wide margin of safety, the excess amounts being rapidly excreted in the urine.

4.9 Overdose

Seek emergency medical attention. Most commonly reported, symptoms of Vitamins & amino acid overdose include nausea and vomiting.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

(i) Pharmaco-therapeutic group: Multivitamins and other minerals, incl. combinations

(ii) ATC code: A11AA03

Mechanism of action: Bunto Blood Tonic Hemoglobin & Vitamins

Syrup. The pharmacokinetics of the active substances would not be different from those naturally derived by food orally.

The following account summarises the pharmacological effects of the vitamins and minerals in Bunto Blood Tonic and describes the conditions caused by deficiency of these.

Vitamin B_1 (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.

Vitamin B_2 (Riboflavine)

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

Vitamin B_6 (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.

Vitamin B_{12} (Cyanocobalamin)

Vitamin B_{12} is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several

metabolic pathways respectively. Deficiency of Vitamin B_{12} interferes with haemopoiesis and produces megaloblastic anaemia.

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.

Iron

Iron, as a constituent of haemoglobin, plays an essential role in oxygen transport. It is also present in the muscle protein myoglobin and in the liver. Deficiency of iron leads to anaemia.

Zinc (Zinc Sulphate)

Zinc is a constituent of many enzymes and is, therefore, essential to the body. It is present with insulin in the pancreas. It plays a role in DNA synthesis and cell division. Reported effects of deficiency include delayed puberty and hypogonadal dwarfism.

Copper (Copper Sulphate)

Copper is implicated directly or indirectly in the pathogenesis of numerous neurological diseases. It deficiency may lead to depression, psychosis, dementia, dysarthria, tremor, chorea and other movement disorders.

5.2 Pharmacokinetic properties

The pharmacokinetics of the active substances would not be different from those naturally derived by food orally.

The following account describes the absorption and fate of each of the active constituents Bunto Blood Tonic

Vitamin B_1 (Thiamine)

Thiamine 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.

Vitamin B_2 (Riboflavine)

Riboflavine 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 riboflavine is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

Vitamin B_6 (Pyridoxine)

Pyridoxine 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.

Vitamin B_{12} (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins.

A study with labelled VitaminB_{12} 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.

Nicotinamide (Nicotinic Acid Amide)

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

Ferric Ammonium citrate (Iron)

Iron is absorbed chiefly in the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and if the iron is in the ferrous state as in ferrous fumarate. In conditions of iron deficiency, absorption is increased and, conversely, it is decreased in iron overload. Iron is stored as ferritin.

Zinc Sulphate (Zinc)

Zinc is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.

Copper Sulphate (Copper)

Copper is absorbed in the gastrointestinal tract, primarily by small intestine. Copper absorption ranges from 12 to 71% in adult humans and from 75 to 84% in infants.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Granulated Sugar, Methylparaben and Propylparaben, Citric Acid, Pineapple Flavour and Liquid Glucose.

6.2 SHELF-LIFE

2 Years.

6.3 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C in a dry place.

6.4 NATURE AND CONTENTS OF CONTAINER

300ml amber colour bottle, packed in an inner carton.

6.5 Pack sizes:

300ml.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.0 APPLICANT /MANUFACTURER

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