1. NAME OF THE MEDICINAL PRODUCT

FINATOR BLOOD TONIC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Ferrous Gluconate	BP	120mg
Vitamin B1	BP	1.0mg
Vitamin B2	BP	1.0mg
Vitamin B6	BP	2.0mg
Vitamin B12	BP	1.0mcg
Nicotinamide	BP	5.0mg
Zinc Sulphate	BP	15mg
Lysine Monohydrchloride	USP	100mg

(overage of vitamins added to compensate for
any loss on storage)

3. PHARMACEUTICAL FORM

Liquid- Tonic

4. Clinical particulars

4.1 Therapeutic indications

Vitamin B1 (Thiamine Mononitrate)

Thiamine is essential CO enzyme for carbohydrate metabolism. Severe deficiency leads to the development of a syndrome know as beri-beri

Vitamin B2 (Riboflavine)

Riboflavine is essential for the utilization of energy from food. Deficiency leas to the development of driboflavonosis. Characterized by Cheilosis, angular stomatitis, glossitis, keratitis and seborrheic dermatitis.

Vitamin B6 (Pyridoxine)

Pyridoxine is involved principally in amino acid metabolism, but is also involved in carbohydrate and fat metabolism.

It is required for the formation of hemoglobin.

Pyridoxine is used in the treatment of depression and other symptoms associated with the premenstrual syndrome and use of oral contraceptives.

Vitamin B12 (Cyanocobalamin)

1) Used in the treatment and prevention of megaloblastic anemias and neurological damage.
2) Used in the treatment of meagaloblastosis caused by prolonged nitrous oxide

anaesthesia which inactivates the vitamin, and in the rare syndrome of congenital transcobalamin deficiency.

Zinc Sulphate

Zinc sulfate is used medically as a dietary supplement. Specifically it is used to treat zinc deficiency and to prevent the condition in those at high risk.

Lysine Monohydrochloride USP

It is required for proper growth and protein synthesis in the body, and has an established role in lowering the cholesterol level by producing carnitine

Nicotinamide
Used to prevent and treat nicotinic acid deficiency (pellagra)
In Summary
FINATOR BLOOD TONIC is a supplement for prevention of Vitamin deficiency in conditions such as galactosaenia, disaccharide intolerance, Phenyl ketonuria and other disorders of carbohydrate or amino acid metabolism, as well as in patient who are on restricted, specialized or synthetic diet.
FINATOR BLOOD TONIC is indicated for the treatment of iron deficiency where there isan associated deficient intake or increased need for B-Complex Vitamins.

4.2 Posology and method of administration

FINATOR BLOOD TONIC is administered
OrallyDosage
Adult: 10-20ml (twice daily)
Children: (6-12years): 5ml twice daily
FINATOR BLOOD TONIC should be taken with or immediately after meal.

4.3 Contraindications

Hypersensitivity to any ingredient of the formulation.
Haemosiderosis, haemochromatosis and patient with hereditary optic nerve atrophy.

4.4 Special warnings and precautions for use

FINATOR BLOOD TONIC is well tolerated at recommended doses. However as is typical of Iron containing formulation there could be darkening of stool, diarrhoea, constipation and vomiting or nausea. The gastro-intestinal irritations can be reduced and controlled by taking blood tonic with or immediately after meals

4.5 Interaction with other medicinal products and other forms of interaction

4.6 Pregnancy and Lactation

In controlled Studies with women, vitamin preparation in Haepler at the usual dosage during the course of the first trimester resulted in no fetal risks. There are no signs indicating a risk , if this type of preparation is taken during the second and third trimesters, the probability of injuring the fetus appears to be very low. Folic acid crosses the placenta. However, adequate and well controlled studies in humans have not shown that folic acid caused adverse effects on the Fetus.

Problems in humans have not been documented with intake of normal daily recommended amountsof Iron.

4.7 Effects on ability to drive and use machines

No influence on the ability to drive or use machines

4.8 Undesirable effects

Long term or excessive administration may cause haemosiderosis, peripheral vascular thrombosis and epigastric pain

Hydralazine and Isoniazid may decrease the effect of pyridoxine.

Pyridoxine may decrease the effect of Levodopa. Folic acid may decrease response to methotrexate.

Folic may lower, serum phenytoin concentrations, phenytoin may lower serum folate concentration.

4.9 Overdose

Large overdoses of water- soluble vitamins are readily excreted in the urine. No emergency procedure or antidote is applicable and any symptoms are rapidly reduced upon withdrawal of the preparation.
Initial symptoms of the iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis rectal bleeding lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur.

Treatment
- To minimize or prevent further absorption of the medication, as follows
Induce vomiting e.g by administration of an emetic
- Gastric lavage with desferrioxamine Solution (2g/L). Then desferrioxamine (5-10g in 50-100ml of water) should be introduced into the stomach to be retained.
- Severe poisoning: shock and or come with high iron levels (serum iron> 90 micromol/L in Children, > 142 micromol/L in adults); immediate supportive measures plus i.v. infusion of desferrioxamine should be instituted.
- Less severe poisoning; i.v desferrioxamine is recommended (1g 4-6hourly in Children; 50mg/kg to a maximum dose of 4g in adults.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutics group: FINATOR BLOOD TONIC, ATC code:B03AE01

Ferrous Gluconate: Ferrous Gluconate is one of the best-tolerated iron supplements. It rapidly supplements elemental iron so that iron deficiency is quickly controlled, thus leading to faster correction of anaemia and replenishment of tissue iron stores.

Each 5ml of Finator Blood Tponic provides 69mg of Ferrous Gluconate thatis equivalent to 14 mg of elemental iron. Thus, when an adult takes the recommended dosage of 1 tablespoonful twice a day, he gets 28 mg of elemental iron which is sufficient amount of elemental iron per day for an adult patient suffering from mild to moderate iron deficiency.

5.2 Pharmacokinetic properties

Iron (Ferrous Gluconate):

Iron irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid section of the stomach and by some dietary acids (such as ascorbic acid) and is more readily affected when the iron is in the ferrous state or is part of the haem complex (haem-iron). Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Only about 5 to 15% of the iron ingested in food is normally absorbed.

Most absorbed iron is bound to transferrin and transported to the bone marrow where it is incorporated into haemoglobin; the remainder is contained within the storage forms,

ferritin or haemosiderin, or as myoglobin, with smaller amounts occurring in haem-containing enzymes or in plasma bound to transferrin. Only very small amounts of iron are excreted as the majority released after the destruction of the haemoglobin molecule is re-used.

5.3 Preclinical safety data

Toxicology
Iron: Iron is a general cellular poison and is directly corrosive to the GI mucosa. Cellular toxicity The absorption of excessive quantities of ingested iron results in systemic iron toxicity. Severe overdose causes impaired oxidative phosphorylation and mitochondrial dysfunction, which can result in cellular death. The liver is one of the organs most affected by iron toxicity, but other organs such as the heart, kidneys, lungs, and the hematologic systems also may be impaired.

MILD TO MODERATE POISONING: Vomiting and diarrhea may occur within 6 hours of ingestion.

SEVERE POISONING: Severe vomiting and diarrhea, lethargy, metabolic acidosis,

shock, GI hemorrhage, coma, seizures, hepatotoxicity, and late onset GI strictures.

soluble vitamin and is regularly removed from the body through urine. One potential issue associated with high dosages of folic acid is that it has a masking effect on the diagnosis of pernicious anaemia (vitamin B12 deficiency).

Vitamin B12:
Vitamin B12 is usually considered a non-toxic substance. Even taking it by injection at high doses does not seem to increase the risk for toxicity

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose (Dry Sugar)
Xanthan Gum
Methyl Paraben
Propyl Paraben
Citric Acid
Ethanol 96%
Caramel Concentrate (Flavor)
Rasberry Essence (Liquid)
Vanilla Flavor (Liquid)
Purified Water
Sodium Hydroxide (pH Adjustment)

6.2 Incompatibilities

None known

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30^{o}C in tight container Protect from light and moisture.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Finator Blood Tonic is available in Amber 200ml Plastic bottle.

6.6 Special precautions for disposal and other handling

No special requirements.

7 APPLICANT/MANUFACTURER

Manufactured by:
FRANPHINO PHARM. CO. LTD
44, Mosalashi Street, Mushin, Lagos, Nigeria.

Marketed by:
ECOMED PHARMA LTD
Plot 32 Lynson Chemical Avenue KM 38
Lagos Abeokuta Expressway,
Sango Ota, Ogun State.