SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

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DR. MEYER'S FEROVITAL BLOOD TONIC

1. NAME OF THE MEDICINAL PRODUCT

Dr. Meyer's Ferovital Blood Tonic (Ferric Ammonium Citrate B.P. 50mg equivalent to Elemental Iron 10mg, Folic Acid B.P. 200mcg, Vitamin B12 (Cyanocobalamin) B.P. 5mcg, Vitamin B1 (Thiamine) HCl B.P 3mg, Vitamin B2 (Riboflavin) Phosphate B.P 0.5mg, Vitamin B6 (Pyridoxine) HCl B.P. 2mg, Vitamin B3 (Nicotinamide) 5mg, Zinc Sulphate Monohydrate 7mg, Copper Sulphate 0.2mg/ 5ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Ferric Ammonium Citrate B.P. 50mg equivalent to Elemental Iron 10mg, Folic Acid B.P. 200mcg, Vitamin B12 (Cyanocobalamin) B.P. 5mcg, Vitamin B1 (Thiamine) HCl B.P 3mg, Vitamin B2 (Riboflavin) Phosphate B.P 0.5mg, Vitamin B6 (Pyridoxine) HCl B.P. 2mg, Vitamin B3 (Nicotinamide) 5mg, Zinc Sulphate Monohydrate 7mg, Copper Sulphate 0.2mg

Excipients:

Nipagin (Methyl Paraben)	10mg
Nipasol (Propyl Paraben)	1mg
Sucrose B.P	2.50gm
Sorbitol 70%	900.00mg
Liquid Glucose	900.00mg
Xanthan Gum	10.00mg
Glycerin	50.00mg
Orange Flavour	0.0025ml
Sodium Hydroxide	0.20mg
Purified Water B.P.	q.s

For Full list of excipients refer section 6.1

3. PHARMACOLOGICAL FORM

Blood Tonic (Liquid Syrup)

Reddish-brown viscous liquid with raspberry and pineapple flavour presented in 200ml amber pet bottle with metallic screw cap packed in a carton with insert and measuring cup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Ferovital is indicated as a dietary supplement preparation for the treatment and prevention of Vitamin deficiencies. malnutrition and general debility and to help maintain health and vitality

4.2 Posology and Method of administration

Adults:	5ml to 10ml to be taken three times daily.
Children (Above 6 Years):	5ml to 10ml to be taken two times daily
2 to 6 Years:	5ml to be taken one or two times daily.
Under 2 Years:	2.5ml to be taken two times daily

4.3 Contraindications

Ferovital should not be given to patients receiving repeated blood transfusions or to patients with anaemias and should not be administered concomitantly with parenteral iron. It helps build blood and boosts immunity

4.4 Special Warnings and Precautions for Use

The use of Ferovital blood tonic in patients with deficiency or increased requirement of vitamins B-complex should be accompanied by specific therapy for the primary illness.

Treatment with Ferovital blood tonic should be continued only until the deficiency is corrected or the need for supplementation exists.

Iron preparations colour the faeces black, which may interfere with tests used for detection of occult blood in the stools. Oral liquid preparations containing iron salts may blacken the teeth. To help prevent this, the mouth may be rinsed with water after use to minimise exposure.

Pyridoxine in Ferovital blood tonic may reduce the therapeutic effect of levodopa in Parkinson's disease.

Riboflavin in Ferovital blood tonic may color the urine yellow.

Ferovital is not indicated in the treatment of pemicious anaemia or megaloblastic anaemia. Inform your doctor your medical history.

Excipient warnings:

This medicine contains sodium parahydroxybenzoates which may cause allergic reactions (possibly delayed).

900mg sorbitol in each 10ml dose. Sorbitol is a source of fructose. Patients with rare hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

Keep out of reach of children.
Do not exceed recommended daily dose/amount

4.5 Interactions with other medications

Although the clinical importance is unknown, thiamine reportedly may enhance the effect of neuromuscular blocking agents.

Iron and tetracyclines reduce the absorption of each other. Iron reduces absorption of zinc, and absorption of oral iron is reduced by zinc.

Iron reduces the absorption of penicillamine, fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, mycophenolate and levothyroxine.

Absorption of iron is reduced with calcium, magnesium and other mineral supplements, bicarbonates, carbonates, zinc and trientine and impaired by antacids, cholestyramine, tea, eggs or milk, but may be increased by ascorbic or citric acid.

Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.

Reduced hypotensive effect of methyldopa.

Niacin reportedly potentiates the hypotensive effect of ganglionic blocking drugs.

4.6 Pregnancy and lactation

As with any other drug, if you are a pregnant or nursing baby, contact your healthcare professional before taking this drug.

4.7 Effects on ability to drive and use machines

The medication does not have any effect on ability to drive and use machines.

4.8 Undesirable effects

This medication is usually well tolerated at the recommended doses. However, there may be few cases of gastro-intestinal upsets due to iron intolerance, this can be minimized by reducing the dosage and also by giving Ferovital Blood Tonic after meals.

4.9 Overdose

All those who have recently ingested more than 20mg/kg should be referred to hospital.

In the first phase of acute iron overdosage, which occurs up to 6 hours after oral ingestion, gastrointestinal toxicity, notably nausea, vomiting, abdominal pain and diarrhoea, predominates. Haematemesis and rectal bleeding may also occur. Other effects may include cardiovascular disorders, such as hypotension and tachycardia, metabolic changes, including acidosis and hyperglycaemia, and CNS depression ranging from lethargy to coma. Patients with only mild to moderate poisoning do not generally progress past this phase.

The second phase may occur at 6 to 24 hours after ingestion and is characterised by a temporary remission or clinical stabilisation.

In the third phase, which occurs between 12 and 48 hours after ingestion, gastrointestinal toxicity recurs together with shock, metabolic acidosis, convulsions, coma, hepatic necrosis and jaundice, hypoglycaemia, coagulation disorders, oliguria or renal failure, and pulmonary oedema. Patients may also experience severe lethargy and myocardial dysfunction.

The fourth phase may occur several weeks after ingestion and is characterised by gastrointestinal obstruction and possibly late hepatic damage.

Treatment:

The following steps are recommended to minimise or prevent further absorption of the medication. Gastric lavage should be considered only within 1 hour of a life-threatening amount being ingested, if the airway can be protected adequately.

Children:

1. Administer an emetic such as syrup of ipecac.

2. Emesis should be followed by gastric lavage with desferrioxamine solution (2 g/l). This should then be followed by the installation of desferrioxamine 5 g in 50-100 ml water, to be retained in the stomach. Inducing diarrhoea in children may be dangerous and should not be undertaken in young children. Keep the patient under constant surveillance to detect possible aspiration of vomitus - maintain suction apparatus and standby emergency oxygen in case of need.

3. Severe poisoning:

In the presence of shock and/or coma with high serum iron levels (serum iron > 90 µmol/l) immediate supportive measure plus IV infusion of desferrioxamine should be instituted. Desferrioxamine 1 5 mg/kg body weight should be administered every hour by slow IV infusion to a maximum 80 mg/kg/24 hours.

Warning:

Hypotension may occur if the infusion rate is too rapid.

4. Less severe poisoning:

IM desferrioxamine 1 g 4-6-hourly is recommended.

5. Serum iron levels should be monitored throughout.

Adults:

1. Administer an emetic.

2.Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using a desferrioxamine solution (2 g/l).

Desferrioxamine 5 g in 50-100 ml water should be introduced into the stomach following gastric emptying. Keep the patients under constant surveillance to detect possible aspiration of vomitus; maintain suction apparatus and standby emergency oxygen in case of need.

3. A drink of mannitol or sorbitol should be given to induce small bowel emptying.

4. Severe poisoning.

In the presence of shock and/or coma with high serum iron levels (> 142 µmol/l) immediate supportive measures plus IV infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5 mg/kg/h by a slow IV infusion up to a maximum of 80 mg/kg/24 hours.

Warning:

Hypotension may occur if the infusion rate is too rapid.

5. Less severe poisoning:

IM desferrioxamine 50 mg/kg up to a maximum dose of 4 g should be given.

6. Serum iron levels should be monitored throughout.

5. PHARMACOLOGICAL PROPERTIES

Elemental iron in the ferric Amonium Citrate form is effective as prophylaxis against iron deficiency and as replacement therapy in mild to moderate iron deficiency anaemia. Good serum rise and haemoglobin response are obtained.

B Complex vitamins function as cofactors of various enzymes which regulate carbohydrate, protein and fat metabolism.[1]

Thiamine (B_1) acts as a cofactor in the decarboxylation of keto acids such as pyruvic acid.

Riboflavin (B_2) plays a vital role in cellular respiratory reactions in conjunction with niacinamide.

Pyridoxine (B_6) takes part in decarboxylation and interconversion of amino acids. It is also required for normal antibody mediated and cell mediated immune responses.[2]

Niacinamide (nicotinamide) plays a vital role in cellular respiration in conjunction with riboflavin

Thus an adequate supply of these water-soluble vitamins is required for the optimum function of various cells and tissues.

These water soluble vitamins are not stored in the body to any significant extent, the excess quantities being excreted in the urine. Therefore, a regular and adequate intake of them is necessary to meet the metabolic requirements.[1]

Deficiencies of water soluble vitamins often co-exist several of them because of their overlapping dietary sources and metabolic interdependence.

Initially the deficiency of these vitamins may be subclinical and demonstrable only by means of biochemical tests. If not corrected at this stage, it may become manifest as various symptoms, including impaired wound healing and increased susceptibility to infection.

Classical deficiency diseases such as beri beri, pellagra and scurvy are rare, whereas mild and subclinical deficiencies are probably more common, even among apparently healthy individuals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Nipagin (Methyl Paraben)	10mg
Nipasol (Propyl Paraben)	1mg
Sucrose B.P	2.50gm
Sorbitol 70%	900.00mg
Liquid Glucose	900.00mg
Xanthan Gum	10.00mg
Glycerin	50.00mg
Orange Flavour	0.0025ml
Sodium Hydroxide	0.20mg
Purified Water B.P.	q.s

6.2 Incompatibilities

None specific

6.3 Shelf-Life

36 Months

6.4 Special Precautions for Storage

Store below 30° C. Replace cap securely.

6.5 Nature and Contents of Container

100 ml and 200ml in Amber coloured pet bottles with metallic screw cap packed in a carton with insert.

6.6 Instructions for Handling

None specific.

7. Applicant / Manufacturer:

Vitabiotics Nigeria Limited

35, Mobolaji Johnson Avenue,

Oregun Industrial Estate,

Ikeja, Lagos,

Nigeria.