SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC) TEMPLATE

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

DR. MEYER'S ORHEPTAL ELIXIR

1. NAME OF THE MEDICINAL PRODUCT

Dr. Meyer's Orheptal Elixir (Liver Extract 23.4mg, Thiamine Hydrochloride 0.98mg, Riboflavine 0.39mg, Nicotinamide 3.92mg, Pyridoxine Hydrochloride 0.39mg, Dexpanthenol 0.51mg, Cyanocobalamin 0.6mcg, Iron (III) Ammonium Citrate 32.18mg, Quinine Hydrochloride 0.15mg, Copper II Chloride 0.15mg/ 5ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Liver Extract 23.4mg, Thiamine Hydrochloride 0.98mg, Riboflavine 0.39mg, Nicotinamide 3.92mg, Pyridoxine Hydrochloride 0.39mg, Dexpanthenol 0.51mg, Cyanocobalamin 0.6mcg, Iron (III) Ammonium Citrate 32.18mg, Quinine Hydrochloride 0.15mg, Copper II Chloride 0.15mg

Excipients:

Nipagin (Methyl Paraben)	3.00mg
Nipasol (Propyl Paraben)	1.50mg
Sucrose B.P	2.50gm
Citric Acid	3.34mg
Alcohol 96%	546.00mg
Malt Extract	2,80mg
Xanthan Gum	10.00mg
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

Elixir

Dark brown liquid syrup presented in 100ml, 300ml & 1 litre pet bottle with metallic screw cap packed in a carton

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Dr. Meyer's Orheptal Elixir 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:	Three teaspoonfuls (15ml) to be taken three times daily with or before meals.
Children:	One teaspoonful (5ml) to be taken three times daily with or before meals.

4.3 Contraindications

Dr. Meyer's Orheptal Elixir 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

Before using Orheptal Blood Tonic, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product pack. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Do not consume if allergic to any ingredient in the medicine
- Do not consume if pregnant or breastfeeding

- Do not use the medicine if suffering from renal or hepatic impairment
- Pregnant, planning to become pregnant or breastfeeding

The use of Dr. Meyer's Orheptal Elixir in patients with deficiency or increased requirement of vitamins B-complex should be accompanied by specific therapy for the primary illness.

Treatment with Dr. Meyer's Orheptal Elixir 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 Dr. Meyer's Orheptal Elixir may reduce the therapeutic effect of levodopa in Parkinson's disease.

Excipient warnings:

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

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

4.5 Interactions with other medications

If you use other drugs or over the counter products at the same time, the effects of Dr. Meyer's Orheptal Elixir may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Dr. Meyer's Orheptal Elixir may interact with the following drugs and products:

- Carbamazepine
- Chloramphenicol
- Ciprofloxacin
- Levofloxacin
- Methotrexate
- Other vitamins or nutritional supplements
- Penicillamine
- Phenytoin
- Primidone
- Tetracyclines

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

The following is a list of possible side-effects that may occur from all constituting ingredients of Dr. Meyer's Orheptal Elixir. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Gastrointestinal distresses
- Black stools
- Gastrointestinal problems
- Stomach pain
- Flushing
- Increased blood sugar level
- Blurred vision
- Rash
- Elevations in liver function tests
- Dizziness
- Allergic sensitization
- Diarrhea
- Liver toxicity
- Headache
- Dr. Meyer's Orheptal Elixir may also cause side-effects not listed here.

If you notice other side-effects not listed above, contact your doctor for medical advice. You may also report side-effects to your local food and drug administration authority.

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 Iron (III) 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.

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

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.

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.

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)	3.00mg
Nipasol (Propyl Paraben)	1.50mg
Sucrose B.P	2.50gm
Citric Acid	3.34mg
Alcohol 96%	546.00mg
Malt Extract	2,80mg
Xanthan Gum	10.00mg
Orange Flavour	0.0025ml
Sodium Hydroxide	0.20mg
Purified Water B.P.	q.s

6.2 Incompatibilities

None specific

6.3 Shelf-Life

24 Months

6.4 Special Precautions for Storage

Store below 30° C. Replace cap securely.

6.5 Nature and Contents of Container

100 ml, 300ml and 1 litre in Amber coloured pet bottles with metallic screw cap packed in a carton.

6.6 Instructions for Handling

None specific.

7. Applicant / Manufacturer:

Farmex Meyer Ltd.,
Km 38, Lagos–Abeokuta Express Road,
Sango-Ota, Ogun State,
Nigeria.