SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

DR. MEYER'S BECOPLEX VITAMIN B-COMPLEX SYRUP

1. NAME OF THE MEDICINAL PRODUCT

Dr. Meyer's Becoplex Syrup (Vitamin B1 (Thiamine Hydrochloride BP) 5mg, Vitamin B2 Sodium Phosphate (Riboflavin 5 Phosphate BP) 2mg, Vitamin B6 (Pyridoxine Hydrochloride B.P.) 2mg, Vitamin B3 (Nicotinamide B.P.) 20mg / 5ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Vitamin B1 (Thiamine Hydrochloride BP)	5mg
Vitamin B2 Sodium Phosphate (Riboflavin 5 Phosphate BP)	2mg
Vitamin B6 (Pyridoxine Hydrochloride B.P.)	2mg
Vitamin B3 (Nicotinamide B.P.)	20mg

Excipients:

Nipagin (Methyl Paraben)	10mg
Nipasol (Propyl Paraben)	1mg
Sucrose B.P	2.750gm
Sorbitol 70%	0.70ml
Orange Flavour	0.0025ml
Purified Water B.P.	q.s

For Full list of excipients refer section 6.1

3. PHARMACOLOGICAL FORM

Syrup

Clear golden yellow viscous liquid with orange & pineapple flavour presented in 100ml amber pet bottle with metallic screw cap packed in a carton with insert and measuring cup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Becoplex is indicated for the prevention and treatment of nutritional deficiencies.

4.2 Posology and Method of administration

For Children above 1 year: one teaspoonful (5 ml) daily, or as advised by the physician.

4.3 Contraindications

Hypersensitivity to any of the ingredients of Becoplex syrup.

4.4 Special Warnings and Precautions for Use

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

Treatment with Becoplex syrup should be continued only until the deficiency is corrected or the need for supplementation exists.

Pyridoxine in Becoplex syrup may reduce the therapeutic effect of levodopa in Parkinson's disease.

Riboflavin in Becoplex syrup may color the urine yellow.

During treatment with Becoplex syrup the urine may give a false positive result for sugar by Benedict's test because of the presence of ascorbic acid.[5] Therefore, a test not affected by ascorbic acid should be used.

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.

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

Hypersensitivity reactions have been reported with thiamine although these are rare.

4.9 Overdose

B-Complex vitamins are water soluble and excess vitamins are expelled in urine. Hence overdose is very rare.

In case of accidental overdose, discontinue use and seek professional assistance immediately.

5. PHARMACOLOGICAL PROPERTIES

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.[3]

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Nipagin (Methyl Paraben)	10mg
Nipasol (Propyl Paraben)	1mg
Sucrose B.P	2.750gm
Sorbitol 70%	0.70ml
Orange Flavour	0.0025ml
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 in Amber coloured pet bottles with metallic screw cap packed in a carton.

6.6 Instructions for Handling

None specific.

7. Applicant / Manufacturer:

Vitabiotics Nigeria Limited
35, Mobolaji Johnson Avenue,
Oregun Industrial Estate,
Ikeja, Lagos,
Nigeria.