

**SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC) TEMPLATE**

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

DR. MEYER'S FOLIC ACID + B₁₂ TABLET

1. Name of the medicinal product

Dr. Meyer's Folic Acid + B12 Tablet

2. Qualitative and quantitative composition

Each tablet contains:

Folic Acid BP	5.00mg
Vitamin B ₁₂ BP	5.00mcg

Excipients:

Nipagin (Methyl Paraben)	0.12mg
Nipasol (Propyl Paraben)	0.06mg
Dicalcium Phosphate	100.00mg
Corn Starch (Paste)	8.00mg
Corn Starch (Bulk)	90.00mg
Corn Starch (Lubricant)	10.00mg
Talcum	2.00mg
Magnesium Stearate	2.00mg
Purified Water	q.s.

3. Pharmaceutical form

Tablet

Yellow circular shaped tablets with 'F/B₁₂' inscribed on one side and 'Ω' on the other side presented in white HDPE plastic securi container with red press on cap containing 100 tablets with insert

4. Clinical particulars

4.1 Therapeutic indications

A dietary supplement preparation for the prevention of megaloblastic nutritional anaemia, and Neural Tube Defect (NTD)

4.2 Posology and method of administration

One tablet to be taken daily with water or as necessary.

Method of administration

For oral use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section.

4.4 Special Warnings and Precautions for use

Dr. Meyer's Folic Acid + B₁₂ is not intended for the treatment of symptomatic deficiencies of the vitamins included.

Especially, it should be noted that the effective treatment of manifest megaloblastic anaemia and pernicious anaemia may need parenteral administration of vitamin B₁₂ at the start of therapy.

Dr. Meyer's Folic Acid + B₁₂ should not be used in patients who have been subject to major resection of the small intestine.

Dr. Meyer's Folic Acid + B₁₂ is not intended for secondary prevention of NTD (neural tube defects), which requires a higher intake of folic acid.

4.5 Interaction with other medicinal products and other forms of interaction

Folic acid

Antiepileptics

Most antiepileptic drugs can cause a decrease in the plasma concentration of folic acid by inhibition of folic acid absorption and/or metabolism.

Folic acid may increase the metabolism of some antiepileptics, such as phenobarbital and phenytoin.

Antibiotics

Some antibiotics can interfere with microbiological tests, which can lead to falsely low results of folic acid concentration measurement in serum and erythrocytes.

Folic acid antagonists

Folic acid antagonists such as methotrexate, pyrimethamine, trimethoprim, sulfonamides and sulfasalazine can inhibit the conversion of folic acid to tetrahydrofolic acid and thus increase the risk of folic acid deficiency.

Cyanocobalamin

The absorption of vitamin B₁₂ from the gastrointestinal tract can be reduced by aminoglycosides, aminosalicic acid, antiepileptics, biguanides (metformin), chloramphenicol, cholestyramine, potassium salts and gastric acid inhibiting substances (for example omeprazole and cimetidine). The clinical relevance of several of these interactions is probably small.

4.6 Fertility, pregnancy and lactation

No known risks.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The undesirable effects are presented according to system organ class and frequency.

Skin and subcutaneous tissue disorders Not known (cannot be estimated from the available data)	Acne like reactions, allergic reactions (urticaria, pruritus, erythema)
Immune system disorders Not known (cannot be estimated from the available data)	Anaphylactic reaction

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Folic acid has low toxicity. No symptoms are to be expected even after high doses. At chronic high dose treatment with *pyridoxine*, some individuals have developed peripheral neuropathies.

Cyanocobalamin has low toxicity. No symptoms are to be expected even after high doses.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin B-complex, plain, ATC code: A11EA.

The amounts of folic acid and vitamin B12 in Dr. Meyer's Folic Acid + B₁₂ have been chosen to provide protection against symptomatic deficiencies especially in elderly people who frequently have malabsorption of folic acid and vitamin B12.

Folic acid and vitamin B12 are necessary for certain transmethylation processes, e.g. in the synthesis of DNA and RNA. Folic acid deficiency leads to megaloblastic anaemia of the same type as in vitamin B12 deficiency.

It has been shown that treatment with a combination of folic acid/vitamin B6/vitamin B12 reduces elevated plasma levels of homocysteine. Homocysteine is a metabolite formed during the metabolism of the essential amino acid methionine. The turnover of homocysteine is influenced by folic acid and vitamin B12 and the plasma level of homocysteine rises markedly in folic acid and vitamin B12 deficiency.

Increased levels of homocysteine have been observed among elderly people.

5.2 Pharmacokinetic properties

Perorally administered *vitamin B12* is absorbed via active and passive mechanisms. Absorption via the active transport mechanism includes intrinsic factor, while vitamin B12 is passively absorbed in the small intestine in the absence of intrinsic factor. The degree of passive absorption is approx. 1% of the administered dose.

An important component of normal vitamin B12 absorption and body conservation of vitamin B12 is enterohepatic circulation. Vitamin B12 is bound to transcobalamines in serum. The transcobalamines in serum are regarded to be saturated at 750-1500 pmol/l of vitamin B12. Not protein bound cyanocobalamin are excreted through glomerular filtration.

Folic acid is rapidly absorbed mainly from the proximal part of the small intestine. Synthetic folic acid is highly bioavailable (approximately 85-100%). Folic acid undergoes enterohepatic circulation. Following absorption, folic acid is largely reduced and methylated in the liver to 5-methyltetrahydrofolic acid, which is the predominant form of circulatory folic acid. The principal storage site is the liver, it is also actively concentrated in the cerebrospinal fluid. Administration of larger doses of folic acid leads to proportionately more of the vitamin being excreted in the urine.

5.3 Preclinical safety data

There are no preclinical data of relevance to the safety evaluation beside those already referred to in the summary of product characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Nipagin (Methyl Paraben)	0.12mg
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Talcum	2.00mg
Magnesium Stearate	2.00mg
Purified Water	q.s.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

Do not use after the expiry date given on the pack.

6.4 Special precautions for storage

Store below 30°C, protect from light.

6.5 Nature and contents of container

White HDPE plastic secure container with red press on caps

Pack sizes of 100 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

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

7. Applicant / Manufacturer:

Vitabiotics Nigeria Limited

35, Mobolaji Johnson Avenue,

Oregun Industrial Estate,

Ikeja, Lagos,

Nigeria.

