1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME: Vitamin B-Complex Tablets

BRAND NAME: SBCO Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PRODUCT NAME: Vitamin B-Complex Tablets

Each sugar coated tablet contains:
Thiamine Nitrate (Vit B_1) ……..1 mg
Riboflavin (Vit B_2)…….....1 mg
Nicotinamide (Vit B_3).……15 mg
Pyridoxine Hydrochloride (Vit B_6)…….1 mg
Excipients……...……q.s

For complete list of excipients refer section 6.1.

3. PHARMACEUTICAL FORM:

Sugar coated Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

SBCO Tablet (B-COMPLEX) is given as nutritional supplement and also given along with Antibiotic therapy. It is also prescribed / given during growth, during lactation, under stress, in fevers and other catabolic conditions such ads hyperthyroidism.
For the treatment of clinical and sub-clinical vitamin B deficiency states (manifestations of which include glossitis, stomatitis, cheilosis, the heart manifestations of beriberi, the skin manifestations of pellagra, corneal vascularisation and polyneuritis)

4.2 Posology and method of administration:

1 - 2 tablets daily according to needs.

1) Route of administration: By mouth (oral)

2) Conditions of administration: One tablet to be taken daily after meals. Or as directed by the physician.

4.3 Contraindications:

This preparation is contra indicated in those who are hypersensitive to any of the component of multivitamin Tablets.

4.4 Special warning and precautions for use

Excipients

Lactose:

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Drug Interactions

Pyridoxine may increase the peripheral metabolism of levodopa, reducing therapeutic efficacy of the latter drug. Therefore, patients with Parkinson's disease who are receiving treatment with plain levodopa should not take vitamin B_6 in doses which greatly exceed the daily requirement. This does not apply when levodopa is combined with a peripheral decarboxylase inhibitor.

4.6 Pregnancy & Lactation

It is safe to prescribe this preparation to pregnant woman but only under the supervision of medical practitioner. The usual precautions should be observed when administering drugs during pregnancy, especially in the first trimester.

In high doses, pyridoxine may interfere with prolactin release and should only be used with caution in nursing mothers.

4.7 Effects on ability to drive and use machines:

Vitamin B-Complex Tablets has no or negligible influence on the ability to drive and use machines.

4.8 Adverse Effects

Allergic reaction (difficulty breathing; closing of throat; swelling of lips, tongue, or face; or hives).

Other, less serious side effects may be more likely to occur. Nausea, constipation, black stools, and diarrhea are among the most common.

4.9 Overdose

Treatment of over dosage is by supportive and symptomatic therapy. In the case of acute over dosage, according to the patient’s condition, supportive therapy may include gastric lavage or emesis.

5.0 PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamics properties

ATC Code: A11EA
ATC Name: Vitamin B-complex,

Nicotinamide is a vitamin (B_3)

Pyridoxine hydrochloride is a vitamin (B_6)

Riboflavin is a vitamin (B_2)

Thiamine mononitrate is a vitamin (B_1)

The vitamin B-complex comprises a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin of the B-complex forms part of a co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

5.2 Pharmacokinetic properties

Nicotinamide is readily absorbed from the GI tract following oral administration and is widely distributed in the body tissues. Small amounts of nicotinamide are excreted unchanged in urine following therapeutic doses, however, the amount excreted unchanged is increased with larger doses.

Pyridoxine is absorbed from the GI tract and is converted to the active form pyridoxal phosphate. It is excreted in the urine as 4-pyridoxic acid.

Riboflavin is absorbed from the GI tract and in the circulation is bound to plasma proteins. Although widely distributed, little is stored in the body, and amounts in excess of requirements are excreted in the urine.

Thiamine is absorbed from the GI tract and is widely distributed to most body tissues. It is not stored to any appreciable extent in the body and amounts in excess of requirements are excreted in the urine as unchanged thiamine or metabolites.

5.3 Preclinical Safety Data: There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SMPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vitamin B-Complex Tablets

List of Excipients:

Tablet core contains:

- Maize Starch BP
- PVPK 30 BP
- Methyl Paraben BP
- Propyl Paraben BP
- Lactose BP
- Talc Powder BP
- Magnesium Stearate BP
- Microcrystalline Cellulose BP

Sugar-coat contains:

- Calcium Carbonate BP
- Sucrose BP
- Gelatine BP
- Sodium Benzoate BP
- Titanium Dioxide
- Colour Tertrazine
- Carnauba Wax BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Store in a cool, dry place below 30°C. Protect from light.
Keep the medicine out of reach of children.

6.5 Nature and contents of container

3 blisters of 10 tablets packed in a printed carton

6.6 Special precautions for disposal and other handling

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

7. APPLICANT

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
NIGERIA

8. WHO PREQUALIFICATION REFERENCE NUMBER

Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION
Not applicable

10. DATE OF REVISION OF THE TEXT
Not applicable