

### 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME OF THE MEDICINAL PRODUCT

**PRODUCT NAME:** Vitamins A, B1, B2, B6, B12, D3, Selenium, Phosphorous, magnesium and Potassium Tablets BP

**BRAND NAME:** Tropitone Tablets

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**PRODUCT NAME:** Vitamins A, B1, B2, B6, B12, D3, Selenium, Phosphorous, magnesium and Potassium BP

Each Sugar coated Tablet contains:

Vitamin A (Acetate) BP	2,000 IU
Vitamin B1 (Thiamine) BP	1 mg
Vitamin B2 (Riboflavin) BP	1 mg
Vitamin B6 (Pyridoxine) BP	1.34 mg
Vitamin B12 (Cyanocobalamin ) BP	1 mcg
Vitamin D3 BP	200 IU
Selenium ( Selenious Acid) USP	50 mcg
Phosphorus ( As Calcium Hydrogen Phosphate ) BP	75mg
Magnesium (As Magnesium Sulphateheptahydrate BP)	1mg
Potassium ( As potassium Sulphate BP )	1 mg

For complete list of excipients refer section 6.1.

#### 3. PHARMACEUTICAL FORM:

Tablet

Red coloured, circular, sugar coated Biconvex tablets and plain on both sides

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic Indication:

##### 4.1 Therapeutic indications

1. As a therapeutic nutritional adjunct where the intake of vitamins and minerals is suboptimal, e.g. in the presence of organic disease such as malignancy and immune deficiency syndromes, such as AIDS.
2. As a therapeutic nutritional adjunct in conditions where the absorption of vitamins and minerals is suboptimal, e.g. malabsorption, inflammatory bowel disease and fistulae, short bowel syndrome and Crohn's disease, and where concurrent medication decreases vitamin and mineral absorption.
3. As a therapeutic nutritional adjunct in convalescence from illness, e.g. where anorexia or cachexia exists and following chemo- or radio-therapy.

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4. As a therapeutic nutritional adjunct in convalescence from surgery, e.g. where nutritional intake continues to be inadequate.
5. As a therapeutic nutritional adjunct for patients on special or restricted diets, e.g. in renal diets and where several food groups are restricted in therapeutic weight reducing diets.
6. As a therapeutic nutritional adjunct where food intolerance exists, e.g. exclusion diets.
7. As an adjunct in synthetic diets, e.g. in phenylketonuria, galactosaemia and ketogenic diets

**4.2 Posology and method of administration:**

Adults and the Elderly

One Tablet daily, preferably taken one hour after meals. Do not exceed the stated dose. The tablet should be swallowed whole with water.

Hypersensitivity to the active substance(s) or to any of the excipients.

**4.4 Special warnings and precautions for use**

Whilst taking TropitoneTablets both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

Do not take TropitoneTablets on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

Patients with thyroid disorders should seek medical advice before taking TropitoneTablets . An allowance should be made for vitamins or minerals obtained from other sources.

**4.5 Interaction with other medicinal products and other forms of interaction**

None anticipated.

**4.6 Pregnancy and lactation**

TropitoneTablets may be administered during pregnancy and lactation at the recommendation of the physician.

**4.7 Effects on ability to drive and use machines**

None anticipated.

**4.8 Undesirable effects**

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common:  $\geq 1/10$

Common:  $\geq 1/100$  to  $< 1/10$

Uncommon:  $\geq 1/1,000$  to  $< 1/100$

Rare:  $\geq 1/10,000$  to  $< 1/1,000$

Very rare:  $< 1/10,000$

Not known: cannot be estimated from the available data

<b>Immune system disorders</b>	<i>Not known:</i> Hypersensitivity reaction (such as rash)
<b>Gastrointestinal disorders</b>	<i>Not known:</i> Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain)

**Reporting of suspected adverse reactions**

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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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

No cases of overdosage due to tropitone therapy have been reported. Any symptoms which may be observed due to the ingestion of large quantities of TropitoneTablets will be due to the fat soluble vitamin content. Hyperglycaemia and metabolic acidosis may also occur. Treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24 - 48 hours, manifest by hypotension coma and hepatocellular necrosis and renal failure.

#### Treatment

The following steps are recommended to minimise or prevent further absorption of the medication:

1. Administer an emetic.
2. Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using desferrioxamine solution (2 g/l). Desferrioxamine 5 g in 50 - 100 ml water should be introduced into the stomach following gastric emptying. Keep the patient 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 ( $>142 \mu\text{mol/l}$ ) immediate supportive measures plus i.v. infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5 mg/kg/h by slow i.v. 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: i.m. desferrioxamine 50 mg/kg up to a maximum dose of 4 g should be given.
6. Serum iron levels should be monitored throughout.
7. Any fluid or electrolyte imbalance should be corrected.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

The following account summarises the pharmacological effects of the vitamins and minerals in Tropitone Tablets and describes the conditions caused by deficiency of these.

##### Vitamin A

Vitamin A plays an important role in the visual process. It is isomerised to the 11-cis isomer and subsequently bound to the opsin to form the photoreceptor for vision under subdued light. One of the earliest symptoms of deficiency is night blindness which may develop into the more serious condition xerophthalmia. Vitamin A also participates in the formation and maintenance of the integrity of epithelial tissues and mucous membranes. Deficiency may cause skin changes resulting in a dry rough skin with lowered resistance to minor skin infections. Deficiency of Vitamin A, usually accompanied by protein-energy malnutrition, is linked with a frequency of infection and with defective immunological defence mechanisms.

##### Vitamin D

Vitamin D is required for the absorption of calcium and phosphate from the gastro-intestinal tract and for their transport. Its involvement in the control of calcium metabolism and hence the normal calcification of bones is well documented. Deficiency of Vitamin D in children may result in the development of rickets.

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### Vitamin B<sub>1</sub> (Thiamine)

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

### Vitamin B<sub>2</sub> (Riboflavine)

Riboflavine is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide which act as co-enzymes in the respiratory chain and in oxidative phosphorylation. Riboflavine deficiency presents with ocular symptoms, as well as lesions on the lips and at angles of the mouth.

### Vitamin B<sub>6</sub> (Pyridoxine)

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.

### Vitamin B<sub>12</sub> (Cyanocobalamin)

Vitamin B<sub>12</sub> is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B<sub>12</sub> interferes with haemopoiesis and produces megaloblastic anaemia.

### Phosphorus (Calcium Hydrogen Phosphate)

Phosphate plays important roles in the osteoblastic and osteoclastic reactions. It interacts with calcium to modify the balance between these two processes. Organic phosphate esters play a key role in the metabolism of carbohydrates, fats and proteins and in the formation of 'high energy phosphate' compounds. Phosphate also acts as a buffer and plays a role in the renal excretion of sodium and hydrogen ions.

### Selenium

Selenium is an essential trace element, deficiency of which has been reported in man. It is thought to be involved in the functioning of membranes and the synthesis of amino acids. Deficiency of selenium in the diet of experimental animals produces fatty liver followed by necrosis.

### Magnesium (Magnesium Sulphateheptahydrate)

Magnesium is essential to the body as a constituent of skeletal structures and in maintaining cell integrity and fluid balance. It is utilised in many of the functions in which calcium is concerned but often exerts the opposite effect. Some enzymes require the magnesium ion as a co-factor.

### Potassium (Potassium Sulfate)

Potassium is the principle cation of intracellular fluid and is intimately involved in the cell function and metabolism. It is essential for carbohydrate metabolism and glycogen storage and protein synthesis and is involved in transmembrane potential where it is necessary to maintain the resting potential in excitable cells. Potassium ions maintain intracellular pH and osmotic pressure. Prolonged or severe diarrhoea may lead to potassium deficiency.

## **5.2 Pharmacokinetic properties**

### Vitamin A

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Except when liver function is impaired, Vitamin A is readily absorbed.  $\beta$ -carotene (as in Tropitone Tablets ) is Provitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; retinol is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolised in the liver and kidney, leaving 30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the faeces and the urine.

#### Vitamin D

The metabolism of ergocalciferol is similar to that of cholecalciferol. Cholecalciferol is absorbed from the gastro-intestinal tract into the circulation. In the liver, it is hydroxylated to 25-hydroxycholecalciferol, is subject to entero-hepatic circulation and is further hydroxylated to 1,25-dihydroxycholecalciferol in the renal tubule cells. Vitamin D metabolites are bound to specific plasma proteins.

#### Vitamin B<sub>1</sub> (Thiamine)

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

#### Vitamin B<sub>2</sub> (Riboflavine)

Riboflavine is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine. In the body riboflavine is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

#### Vitamin B<sub>6</sub> (Pyridoxine)

Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

#### Vitamin B<sub>12</sub> (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B<sub>12</sub> showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

#### Vitamin C (Ascorbic Acid)

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.

#### Phosphorus (Calcium Hydrogen Phosphate)

The body contains from 600 - 800 g of phosphorus, over 80% of which is present in the bone as phosphate salts, mainly hydroxyapatite crystals. The phosphate in these crystals is available for exchange with phosphate ions in the extra-cellular fluids.

#### Selenium( selenious acid )

Although it has been established that selenium is essential to human life, very little information is available on its function and metabolism.

#### Magnesium (Magnesium Sulphateheptahydrate)

Magnesium salts are poorly absorbed from the gastro-intestinal tract; however, sufficient magnesium will normally be absorbed to replace deficiency states. Magnesium is excreted in both the urine and the faeces but excretion is reduced in deficiency states.

#### Potassium Sulfate (Potassium)

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Potassium salts are absorbed from the gastro-intestinal tract. Potassium is excreted in the urine, the faeces and in perspiration. Urinary excretion of potassium continues even when intake is low.

### **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**

- Povidone BP
- Isopropyl Alcohol BP
- DiCalcium phosphate BP
- ButylatedHydroxytolueneBP
- Polysorbate 80 BP
- Maize Starch BP
- Methyl Hydroxybenzote BP
- Propyl Hydroxybenzoate BP
- Purified Talc BP
- Magnesium Stearate BP
- Shellac IH (Bleached)
- Methylene Chloride BP
- Sucrose BP
- Titanium Dioxide BP
- Acacia BP(Powdered)
- Carmoisine IH
- Ponceau IH
- Carnauba Wax BP

### **6.2 Incompatibilities**

No major incompatibilities are known.

### **6.3 Shelf life**

36 months, as packaged for sale.

### **6.4 Special precautions for storage**

Store in a cool dry place at a temperature not exceeding 25°C.

Protect from light.

### **6.5 Nature and contents of container**

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**Product Name: Tropitone Plus Tablets (Vitamins A, B1, B2, B6, B12, D3, Selenium, Phosphorous, magnesium, Potasium, Ginseng Extract and Aloevera)**

The product is presented in press-thru blister packs, each blister strip containing 30 TropitoneTablets. The blister strip is composed of PVC with a printed aluminium foil lidding. The foil is printed (red on Silver) with the number of vitamins and minerals per tablet and the daily dose.

The product is available in packs of 30tablets

**NAFDAC Reg.No : 04-3884**

**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**

**Business Address:**

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