1.3.1 Summary of Product Characteristics (SmPC)

1. Name of Medicinal Product

A TO ZED CAPSULES

MULTIVITAMIN, IRON & MINERALS CAPSULES

2. Qualitative and Quantitative Composition

2.1. Qualitative declaration:

Composition of the Drug product:

Each Soft Gelatin Capsule contains:

Vitamin A (As Palmitate) BP...…… 2500 I.U

Vitamin B1 BP 1mg

Vitamin B2 BP 1mg

Vitamin B6 BP 0.50mg

Vitamin B12 BP.....0.50mcg

Vitamin E BP 5mg

Vitamin D3 BP .....100 IU

Nicotinamide BP……...15mg

Folic Acid BP……50mcg

Copper (From Copper Sulphate) BP…….0.45mg

Iodine (From Potassium Iodide) BP……..0.075 mg

Manganese (from Manganese Sulphate) USP……..…….0.5mg

Calcium (From Dibasic Calcium Phosphate) BP…….…..190mg

Phosphorous (From Dibasic calcium Phosphate) BP 140mg

Iron (From Dried Ferrous sulphate) BP 10mg

Potassium (From Potassium Sulphate) BP.....2mg

Zinc (From Zinc oxide) BP 0.15mg

Excipients ……..…….....…….. Q.S.

Approved colour are used in capsule shell.

Appropriate overages of vitamins are added to compensate for loss on storage.

Qualitative & Quantitative Composition Formula:

Batch Size: 408000 Nos Soft gelatin Capsules

Sr. No.	Name of Ingredient	Specification	Wt. per Capsules (mg)	O.A % per Caps	Qty. per Caps. With O.A % (mg)	Total Qty per Batch (kg)	Function
Active Ingredients							
1.	Vitamin A Palmitate (1.7MIU/GM)	B.P.	1.4705		1.4705	0.600	**Active**
2.	Vitamin B1	B.P.	1	20	1.2	0.490	**Active**
3.	Vitamin B2	B.P.	1	20	1.2	0.490	**Active**
4.	Vitamin B6	B.P.	0.5	20	0.6	0.245	**Active**
5.	Vitamin B12	B.P.	0.0005	50	0.001	0.306	**Active**
6.	Vitamin E	B.P.	5	5	5.25	2.142	**Active**
7.	Vitamin D3	B.P.	0.0025	50	0.005	1.530	**Active**
8.	Nicotinamide	B.P.	15	20	18	7.344	**Active**
9.	Folic Acid	B.P.	0.05	25	0.0625	0.024	**Active**
10.	Copper Sulphate anhydrous	B.P.	1.13		1.13	0.461	**Active**
11.	Potassium Iodide	B.P.	0.0981		0.0981	3.464	**Active**
12.	Manganese Sulphate	U.S.P.	1.53		1.53	0.628	**Active**
13.	Dibasic Calcium Phosphate	B.P.	254.78		254.78	263.172	**Active**
14.	Ferrous Sulphate	B.P.	27.38		27.38	11.098	**Active**
15.	Zinc Oxide	B.P.	0.4117		0.4117	0.253	**Active**
Excipients							
16.	Soyabean oil	USP NF	289.21		289.21	51.759	**Diluents**
17.	Light Liquid	B.P.	389.86		389.86	155.550	**Thickeni**

	Paraffin						**ng agent**
18.	Yellow Bees Wax	B.P.	5		5	2.040	**Thickening agent**
19.	Butylated Hydroxy Anisole	B.P.	0.08		0.08	0.033	**Antioxidant**
20	Butylated Hydroxy Toluene	B.P.	0.02		0.02	0.00612	**Antioxidant**
21.	Soya Lecithin	U.S.P.	50		50	10.200	**Emulsifying agent**
Total					**1250 mg**	**510.00 kg**	

3. Pharmaceutical Form

Soft gelatin Capsules

Blood Red colored, oblong shape soft gelatin capsule containing Yellow Coloured homogenous oily paste. Printed with "A to ZED" with white ink.

4. Clinical Particulars

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.

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

Children under 12 years of age

A TO ZED CAPSULES are not recommended for this age group.

4.3 Contraindications

Hypercalcaemia, haemochromatosis and other iron storage disorders.

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

A TO ZED CAPSULEScontain soya bean oil. Patients allergic to peanut or soya should not take this medicine.

4.4 Special warnings and precautions for use

Whilst taking A TO ZED CAPSULES 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 A TO ZED CAPSULE Son an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal.

This medicine contains E123 (amaranth) and E124 (ponceau 4R red) which may cause allergic reactions.

Evidence from Randomised Control Trials suggests that high doses (20-30 mg/day) b-carotene intake may increase the risk of lung cancer in current smokers and those previously exposed to

asbestos. This high-risk population should consider the potential risks and benefits of A TO ZED CAPSULES, which contain 4.5mg per recommended daily dose, before use.

Patients with thyroid disorders should seek medical advice before taking A TO ZED CAPSULES. 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. Use in pregnancy and lactation:

A TO ZED CAPSULES 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 System Organ Classes.

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

Very common: ≥1/10

Common: ≥1/100 to <1/10

Uncommon: ≥1/1,000 to <1/100

Rare: ≥1/10,000 to <1/1,000

Very rare: <1/10,000

Not known: cannot be estimated from the available data

Immune system disorders	*Not known:* Hypersensitivity reaction (such as rash)
Gastrointestinal disorders	*Not known:* Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain)

4.9. Overdose:

No cases of overdosage due to Forceval therapy have been reported. Any symptoms which may be observed due to the ingestion of large quantities of A TO ZED CAPSULESwill be due to the fat soluble vitamin content. If iron overdosage is suspected, symptoms may include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. 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 μmol/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 A TO ZED CAPSULES 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.

Vitamin B_1 (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_2 (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_6 (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_{12} (Cyanocobalamin)

Vitamin B_{12} 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_{12} interferes with haemopoiesis and produces megaloblastic anaemia.

Iron

Iron, as a constituent of haemoglobin, plays an essential role in oxygen transport. It is also present in the muscle protein myoglobin and in the liver. Deficiency of iron leads to anaemia.

Copper (Copper Sulfate)

Traces of copper are essential to the body as constituents of enzyme systems involved in oxidation reactions.

Zinc (Zinc Sulfate)

Zinc is a constituent of many enzymes and is, therefore, essential to the body. It is present with insulin in the pancreas. It plays a role in DNA synthesis and cell division. Reported effects of deficiency include delayed puberty and hypogonadal dwarfism.

Iodine (Potassium Iodide)

Iodine is an essential constituent of the thyroid hormones.

5.2 Pharmacokinetic properties

The following account describes the absorption and fate of each of the active constituents of A TO ZED CAPSULES.

Vitamin A

Except when liver function is impaired, Vitamin A is readily absorbed. β-carotene (as in A TO ZED CAPSULES 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_1 (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_2 (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_6 (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_{12} (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B_{12} 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 E

Vitamin E is absorbed from the gastro-intestinal tract. Most appears in the lymph and is then widely distributed to all tissues. Most of a dose is slowly excreted in the bile and the remainder is eliminated in the urine as glucuronides of tocopheronic acid or other metabolites.

Calcium (Calcium Hydrogen Phosphate)

A third of ingested calcium is absorbed from the small intestine. Absorption of calcium decreases with age.

Ferrous Fumarate (Iron)

Iron is absorbed chiefly in the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and if the iron is in the ferrous state as in ferrous fumarate. In conditions of iron deficiency, absorption is increased and, conversely, it is decreased in iron overload. Iron is stored as ferritin.

Copper Sulfate (Copper)

Copper is absorbed from the gastro-intestinal tract and its major route of excretion is in the bile.

Potassium Sulfate (Potassium)

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.

Zinc

Zinc is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.

Manganese Sulfate (Manganese)

Manganese salts are poorly absorbed.

Potassium Iodide (Iodine)

Iodides are absorbed and stored in the thyroid gland as thyroglobulin. Iodides are excreted in the urine with smaller amounts appearing in the faeces, saliva and sweat.

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 SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sr. No.	Excipients	Specification
1	Soyabean oil	USP NF
2	Light Liquid Paraffin	B.P.
3	Yellow Bees Wax	B.P.
4	Butylated Hydroxy Anisole	B.P.
5	Butylated Hydroxy Toluene	B.P.
6	Soya Lecithin	U.S.P.

6.2 Incompatibilities

None Known

6.3 Shelf life

24 years

6.4 Special precautions for storage

Store in a cool & dry Place, Protect from Light.

6.5 Nature and contents of container

A TO ZED CAPSULES: 2 X 15 capsules

Each Alu/PVC Blisters containing 15 capsules such 2 Alu/PVC blisters are packed in a carton with pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7- Marketing Authorization Holder:

GREENLIFE PHARMACEUTICALS LTD.

2, Bank Lane, Off. Town Planning way,

Ilupeju, Lagos State, Nigeria.

8- Marketing Authorization Number (s):

Product license / registration Number (s)

9- Manufacturer Name:

BRIYOSIS SOFT CAPS PVT. LTD.

S.R No. 176/1-1, Opp. L K India, Jarod-Rasulabad Road,At & Post: Jarod, Dist: Vadodara