SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

Becoshel Syrup

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Each 5ml contains: Thiamine Hydrochloride (Vitamin B1) 5.0mg, Riboflavin (Vitamin B2) 2.0mg, Nicotinamide (Vitamin B3) 20.0mg, Pyridoxine Hydrochloride (Vitamin B6) 2.0mg.

3. PHARMACEUTICAL FORM

Syrup

Red, clear syrupy liquid with pleasant aroma

1. CLINICAL PARTICULARS

2. Therapeutic Indications

Becoshel Syrup is indicated for the stimulation of appetite, restoring energy and enhances healing in debilitated or convalescent individuals. It also used as a prophylactic during growth, pregnancy and lactation, pre and post-operative care, during sulphonamide and antibiotic therapy.

It is also used in malnutrition, infections and wasting diseases, debility, exhaustion and fatigue, neuritis, neurasthenia. .

3. Posology and Method of Administration

For oral administration only

As directed by the physician OR

Age	No. of teaspoonfuls (5ml)
< 12 years	1 (5ml)
> 12 years	2 (10ml)

4. Contraindications

Vitamins are not synthesized in the body. Vitamins are also not synthesized in small or insufficient quantities and hence their administration according to need, as they are parts of human body components.

5. Special Warnings and Precautions for Use

Becoshel Syrup should be given cautiously to patients with a history of peptic ulcer disease and to patients with diabetes mellitus, gout or impaired liver function.

Keep the medicine out of reach of children.

6. Interaction with other medicinal products and other forms of interaction

Pyridoxine Hydrochloride (Vitamin B6) may reduce the effectiveness of levodopa.

7. Adverse Reactions

Flushing, a sensation of heat, faintness and a pounding head, dryness of the skin, abdominal cramps, diarrhoea, nausea, vomiting anorexia activation of peptic ulcer and reduction in glucose tolerance.

8. Overdose

Anorexia, loss of weight, irritability, vomiting , other gastro-intestinal disturbance, dryness of skin, pruritus, hyperpigmentation, abdominal cramps, diarrhea, nausea, haematological response in patients with folate deficiency, htyperoxaluria and the formation of renal calcium oxalate calculi.
Treatment of Overdose
The therapy should be discontinued and initiate symptomatic and supportive treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1.Pharmacodynamic Properties

Thiamine Hydrochloride (Vitamin B1) is a water soluble vitamin that is a co-enzyme for carbohydrate metabolism. It has been found that Thiamine Hydrochloride helps in the protection against lead-induced lipid peroxidation in rat liver and kidney.

Thiamine is a vitamin with antioxidant, erythropoietin, cognition-and mood-modulatory, ant atherosclerotic, putative ergogenic, and detoxification activities. Thiamine has been found to protect against lead-induced lipid peroxidation in rat liver and kidney. Thiamine deficiency results in selective neuronal death in animal models. The neuronal death is associated with increased free

radical production, suggesting that oxidative stress may play an important early role in brain damage associated with thiamine deficiency.

Thiamine plays a key role in intracellular glucose metabolism and it is thought that thiamine inhibits the effect of glucose and insulin on arterial smooth muscle cell proliferation. Inhibition of endothelial cell proliferation may also promote atherosclerosis. Endothelial cells in culture have been found to have a decreased proliferative rate and delayed migration in response to hyperglycemic conditions. Thiamine has been shown to inhibit this effect of glucose on endothelial cells.

Riboflavin (Vitamin B2) is an easily absorbed water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolism process. It has a key role of maintaining human health. Like other B vitamins, it supports energy production by aiding in the metabolizing of fats, carbohydrates and proteins. It is also required for red blood cell formation and respiration, antibodies production and for regulation human growth and reproduction.

It is essential for healthy skin, nails, hair growth and general good health, including regulating thyroid activity. Riboflavin also helps in the prevention or treatment of many types of eye disorders, including some cases of cataracts.

Nicotinamide (Vitamin B3) is a water soluble vitamin converted to Nicotinamide Adenine Dinucleotide and Nicotinamide Adenine Dinucleotide Phosphate in the body, both of which are co-enzymes important in the electron transfer in respiratory reactions. It is indicated for the prevention and treatment of Vitamin B3 deficiency states.

Nicotinamide also acts to reduce LDL cholesterol, triglycerides and HDL cholesterol.

Pyridoxine Hydrochloride (Vitamin B6) is a water soluble vitamin involved in the carbohydrate and fat blood pressure in a small group of subjects with essential hypertension.

Vitamin B6 has been found to lower systolic and diastolic blood pressure in a small group of subjects with essential hypertension. Hypertension is another risk factor for atherosclerosis and coronary heart disease. Another study showed pyridoxine hydrochloride to inhibit ADP- or

epinephrine-induced platelet aggregation and to lower total cholesterol levels and increase HDL-cholesterol levels, again in a small group of subjects. Vitamin B6, in the form of pyridoxal 5'-phosphate, was found to protect vascular endothelial cells in culture from injury by activated platelets. Endothelial injury and dysfunction are critical initiating events in the pathogenesis of atherosclerosis. Human studies have demonstrated that vitamin B6 deficiency affects cellular and humoral responses of the immune system. Vitamin B6 deficiency results in altered lymphocyte differentiation and maturation, reduced delayed-type hypersensitivity (DTH) responses, impaired antibody production, decreased lymphocyte proliferation and decreased interleukin (IL)-2 production, among other immunologic activities.

5.2.Pharmacokinetic Properties

Thiamine Hydrochloride (Vitamin B1)

Absorption: It is absorbed by both diffusion and active transport mechanism.

Distribution: Thiamine Hydrochloride is widely distributed in all tissues, with highest concentrations in liver, brain, kidney and heart.

Metabolism: Thiamine Hydrochloride undergoes rapid metabolism. Thiamine + ATP thiamine pyrophosphate (cocarboxylase) coenzyme.

Elimination: Excess Thiamine Hydrpchloride is excreted in the urine. Depletion of Vitamin B1 occurs about 3 weeks with absence of Thiamine in diet.

Riboflavin (Vitamin B2)

Absorption: Riboflavin is well absorbed from the upper gastrointestinal tract by an active transport process.

Distribution: It crosses the placenta and enters the breast milk. It is widely distributed.

Metabolism: Riboflavin is converted into flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD), which are the active coenzymes.

Elimination: Amounts that are excess of the requirements are excreted unchanged by the kidneys.

Nicotinamide (Vitamin B3)

Absorption: Nicotinamide, also known as Niacin, is rapidly and extensively absorbed from GI tract.

Metabolism: Rapid and extensive first-pass metabolism of Niacin in the liver.

Elimination: It is eliminated in the urine.

Pyridoxine Hydrochloride (Vitamin B6)

Absorption: Pyridoxine Hydrochloride is absorbed by passive diffusion in the jejenum and to a lesser extent in the ileum.

Distribution: Pyridoxine Hydrochloride is primarily stored in the liver, lesser amount in the muscle and brain. Not protein bound.

Metabolism: It is metabolized in the liver and converted to 4-pyridoxic acid metabolite.

Elimination: It is mostly eliminated as 4-pyridoxic acid in the urine.

5.3.Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1.List of excipients

Refined Sugar Syrup, Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Sodium Chloride, Anhydrous Citric Acid, Strawberry Flavour Liquid, Tartaric Acid, Colour Amaranth Powder, Sodium Hydroxide and Purified Water.

6.2.Incompatibilities

None known

6.3.Shelf life

36 months

6.4.Special precautions for storage

Store in a cool dry place below 300C. Protect from light. Keep out of reach of children

6.5.Nature and contents of container

Packed in 100ml amber coloured glass bottles in a unit carton with an insert.

6.6.Special precautions for disposal and other handling

No special requirements

7.0 Name & Address of Manufacturer

Name: Beta Healthcare International Ltd
Address: Plot No. LR 209/6554, Mogadishu Road, Industrial Area, Nairobi,
Postal Address: P.O. Box 42569-00100, Nairobi, Kenya
Telephone: +254202652042/89
Telefax: +25420556198
Email: info@ke.betashelys.com

8.0 Marketing authorization number

TAN 22 HM 0166

9.0 Date of first authorization/renewal of authorization

04th May, 2022

10. Date of revision of the text