CTD MODULE 1 ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION	
Product Name :	**BECOREN TABLETS** **(Vitamin B_1 Mononitrate 0.5mg, Vitamin B_2 BP 0.5mg, Vitamin B_6 BP 0.5mg and Niacinamide BP 7.5mg)**

1.5 Product Information: BECOREN TABLETS

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: BECOREN TABLETS
Strength:
Each tablet contains Vitamin B1 Mononitrate BP 0.5mg, Vitamin B2 BP 0.5mg, Vitamin B6 BP 0.5mg and Niacinamide BP 7.5mg.
Pharmaceutical form: Oral Tablets

2. Qualitative and Quantitative composition:

Qualitative composition and Quantitative composition:

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**			
		Each tablet contains Vitamin B1 Mononitrate BP 0.5mg, Vitamin B2 BP 0.5mg, Vitamin B6 BP 0.5mg and Niacinamide BP 7.5mg.			
		Quantity in mg per tablet	**%**	**Quantity in Kg Per 2,000,000 Tablets**	**%**
Contents of **BECOREN TABLETS**					
Thiamine Mononitrite	Active	0.500	0.26	1.100	0.26
Riboflavin 5D Phosphate	Active	0.500	0.26	1.500	0.26
Pyridoxine Hydrochloride	Active	0.500	0.26	1.200	0.26
Niacinamide	Active	7.500	3.86	16.500	3.86
Maize starch (Mixing)	Diluent	80.000	41.15	160.000	41.15
Dicalcium phosphate	Nutrient	39.35	20.24	78.700	20.24
Maize starch (Paste)	Binder	20.000	10.29	40.000	10.29
Sodium methyl paraben	Preservative	0.040	0.02	0.080	0.02
Sodium propyl paraben	Preservative	0.020	0.01	0.040	0.01
Lactose	Diluent	40.000	20.57	80.000	20.57
Microcrystalline cellulose	Disintegrant	5.000	2.57	10.000	2.57

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Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**			
		Each tablet contains Vitamin B1 Mononitrate BP 0.5mg, Vitamin B2 BP 0.5mg, Vitamin B6 BP 0.5mg and Niacinamide BP 7.5mg.			
		Quantity in mg per tablet	**%**	**Quantity in Kg Per 2,000,000 Tablets**	**%**
Magnesium stearate	Lubricant	1.000	0.51	2.000	0.51
Total	NA	194.41	100.00	391.12	100.00

3. Pharmaceutical form: Oral Tablets

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4. Clinical particular's:

4.1 Therapeutic indication:

1) 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:

Adults (including elderly) and children over 3 years: One to two tablets three times daily.
Children under 3 years: Not recommended.

Method of administration

For oral administration.

4.3 Contraindication:

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warning and precaution 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 Interactions with other medicinal products and other forms of 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 B6 in doses which greatly exceed the daily requirement. This does not apply when levodopa is combined with a peripheral decarboxylase inhibitor.

Additional information on special populations:

Not Applicable

Pediatric population:

Not Applicable

4.6 Fertility, pregnancy and lactation:

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:
None known.

4.8 Undesirable effects:
Toxic effects are unlikely since any excess vitamin B is excreted.

4.9 Overdose and Treatment:
Excess vitamin B is readily excreted , therefore no serious problems are anticipated for the administration of vitamin B in this form.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

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.

Riboflavine 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:

Not applicable

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6. Pharmaceutical Particulars:

6.1 List of excipients

Becoren contains the following excipients:

Dicalcium phosphate, Maize starch, Sodium methyl paraben, Sodium propyl paraben, Lactose, Microcrystalline cellulose, Magnesium stearate.

6.2 Incompatibilities

None known

6.3 Shelf life

24 Months

6.4 Special precaution for storage

Store in a well closed container. Keep out of reach of children. Protect from light.

6.5 Nature and contents of container

Aluminium /PVC foil blister strip of 10x10 tablets in a unit box along with pack insert.

6.6 Special precautions for disposal

No special precaution

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES:

Marketing Authorization Holder:
Rene Industries Ltd
Address: PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

Manufactured by:
Rene Industries Ltd
Address: PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

8. MARKETING AUTHORISATION NUMBER:

Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION:

Not Applicable

10. DATE OF REVISION OF THE TEXT:

Not Applicable

11. DOSIMETRY (IF APPLICABLE):

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE):

Not Applicable