

**CTD MODULE 1**  
**ADMINISTRATIVE INFORMATION AND**  
**PRODUCT INFORMATION**

<b>Product Name :</b>	<b>VITAREN SYRUP</b> <b>(Vitamin A (as Palmitate) BP1500 I.U, Thiamine HCl (Vitamin B1) BP 1 mg, Riboflavin Sodium Phosphate (Vitamin B2) BP 1 mg, Pyridoxine HCl (Vitamin B6) BP 0.5 mg, Cholecalciferol (Vitamin D) BP 100 I.U, Nicotinamide BP 10 mg)</b>
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**1.5 Product Information: VITAREN SYRUP**

**1.5.1 Prescribing information (Summary of products characteristics):**

**1. Name of the Medicinal Product: VITAREN SYRUP**

**Strength:**

Each 5 ml contains Vitamin A (as Palmitate) BP1500 I.U, Thiamine HCl (Vitamin B1) BP 1 mg, Riboflavin Sodium Phosphate (Vitamin B2) BP 1 mg, Pyridoxine HCl (Vitamin B6) BP 0.5 mg, Cholecalciferol (Vitamin D) BP 100 I.U, Nicotinamide BP 10 mg.

**Pharmaceutical form:** Syrup

**2. Qualitative and Quantitative composition:**

**Qualitative composition and Quantitative composition:**

Component and quality standard (and grade, if applicable)	Function	Strength (label claim)			
		Quantity in mg per 5ml	%	Quantity in kg per 1000L Tonic	%
Each 5 ml contains Vitamin A (as Palmitate) BP1500 I.U, Thiamine HCl (Vitamin B1) BP 1 mg, Riboflavin Sodium Phosphate (Vitamin B2) BP 1 mg, Pyridoxine HCl (Vitamin B6) BP 0.5 mg, Cholecalciferol (Vitamin D) BP 100 I.U, Nicotinamide BP 10 mg					
<b>Contents of VITAREN SYRUP</b>					
Vitamin A Palmitate	Active	1500 IU	0.08	0.194	0.08
Cholecalciferol	Active	100 IU	0.0002	0.00055	0.0002
Riboflavin sodium	Active	1.000	0.09	0.220	0.09
Thiamin HCl	Active	1.000	0.09	0.220	0.09
Nicotinamide	Active	10.000	0.78	2.000	0.78
Pyridoxine HCl	Active	0.500	0.04	0.110	0.04
Propylene glycol	Diluent	200.000	15.57	40.000	15.57
Ascorbic acid	Supplement	20.000	1.95	5.000	1.95
Sodium methyl paraben	Preservative	1.000	0.08	0.200	0.08
Sodium propyl paraben	Preservative	0.500	0.03	0.100	0.03
Bronopol	Antimicrobial Preservative	1.000	0.08	0.200	0.08

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EDTA Disodium	Chelating agent	5.000	0.39	1.000	0.39
Tween 80	Stabilizer	20.000	1.56	4.000	1.56
Tutti fruity flavour	Flavour	0.002	0.16	0.400 L	0.16
Flavour orange	Flavour	0.004	0.31	0.800 L	0.31
Sodium citrate	Buffer	12.500	0.97	2.500	0.97
Sucrose	Sweetener	1000.000	77.84	200.00	77.84
Purified water	Solvent	q.s 5ml	-	q.s 1000L	-
Total	NA	5ml	100.00	256.94	100.00

**3. Pharmaceutical form: Syrup**

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**4. Clinical particular's:**

**4.1 Therapeutic indication:**

Not available

**4.2 Posology and method of administration:**

Not available

**4.3 Contraindication:**

Not available

**4.4 Special warning and precaution for use:**

Not available

**4.5 Interactions with other medicinal products and other forms of interactions:**

Not available

**Additional information on special populations:**

Not Applicable

**Pediatric population:**

Not Applicable

**4.6 Fertility, pregnancy and lactation:**

Not available

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

Not available

**4.8 Undesirable effects:**

Not available

**4.9 Overdose and Treatment:**

Not available

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**5. Pharmacological Properties:**

**5.1 Pharmacodynamic properties:**

Not available

**5.2 Pharmacokinetic properties:**

Not available

**5.3 Preclinical safety data:**

Not available

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**6. Pharmaceutical Particulars:**

**6.1 List of excipients**

Vitaren Syrup contains the following excipients:

Propylene glycol, Ascorbic acid, Sodium methyl paraben, Sodium propyl paraben, Bronopol, EDTA Disodium, Tween 80, Tutti fruity flavor, Flavour orange, Sodium citrate, Sucrose, Purified water.

**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**

Clear yellow syrup filled in amber glass bottles and sealed with ROPP caps.

**6.6 Special precautions for disposal**

No special precaution

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**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