1.5 Product Information: RENE-CPM TABLETS

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: RENE-CPM TABLETS

Strength: Each tablet contains Chlorpheniramine Maleate 4.0mg

Pharmaceutical form: Tablet

2. Qualitative and Quantitative composition:

Qualitative composition:

Sr. No.	Ingredient	Specification	Uses
1.	Chlorpheniramine Maleate	BP	Active
2.	Lactose	BP	Binder
3.	Maize starch (Mixing)	BP	Diluent
4.	Dicalcium phosphate	BP	Abrasive
5.	Maize starch (Paste)	BP	Binder
6.	Tartrazine supra	BP	Colour
7.	Sodium methyl paraben	BP	Preservative
8.	Sodium propyl paraben	BP	Preservative
9.	Sodium starch glycollate	BP	Disintegrant
10.	Magnesium stearate	BP	Lubricant

CTD MODULE 1 ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION	
Product Name :	**RENE-CPM TABLETS (Chlorpheniramine Maleate 4mg)**

Quantitative composition:

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)** Each tablet contains Chlorpheniramine Maleate BP 4mg			
		Quantity in mg per tablet	**%**	**Quantity in Kg Per 3,000,000 Tablets**	**%**
Contents of **RENE-CPM TABLETS**					
Chlorpheniramine Maleate	Active	4.00	3.81	12.000	3.81
Lactose	Binder	30.00	28.57	90.000	28.57
Maize starch (Mixing)	Diluent	28.00	26.67	84.000	26.67
Dicalcium phosphate	Abrasive	35.00	33.33	105.000	33.33
Maize starch (Paste)	Binder	4.00	3.81	12.000	3.81
Tartrazine supra	Colour	0.025	0.02	0.075	0.02
Sodium methyl paraben	Preservative	0.200	0.19	0.600	0.19
Sodium propyl paraben	Preservative	0.09	0.08	0.270	0.08
Sodium starch glycollate	Disintegrant	2.185	2.09	6.555	2.09
Magnesium stearate	Lubricant	1.500	1.43	4.500	1.43
Total	NA	105.00	100.00	315.00	100.00

3. Pharmaceutical form: Tablet

4. Clinical particular's:

4.1 Therapeutic indication:

The tablets are indicated for symptomatic control of all allergic conditions responsive to antihistamines including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions and insect bites.
Also indicated for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and method of administration:

Posology

Adults and children over 12 years:
1 tablet (4mg) every 4 to 6 hourly.
Maximum daily dose: 6 tablets (24mg) in any 24 hours.
Elderly:
The elderly are more likely to experience neurological anticholinergic effects.
Consideration should be given to using a lower daily dose (e.g. a maximum of 12 mg in any 24 hours).
Children aged 6 - 12 years:
½ tablet (2mg) 4 to 6 hourly.
Maximum daily dose: 3 tablets (12mg) in any 24 hours.
Not recommended for children under the age of 6 years.

Method of administration

For oral administration only
Do not exceed the stated dose or frequency of dosing.

4.3 Contraindication:

• Hypersensitivity to the active substance, antihistamines or to any of the excipients listed in section 6.1.
• The anticholinergic properties of Chlorpheniramine are intensified by monoamine oxidase inhibitors (MAOIs). The tablets are therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.

4.4 Special warning and precaution for use:

Chlorpheniramine in common with other drugs having anticholinergic effects, should be used with caution in epilepsy, raised intra-ocular pressure including glaucoma, prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis or asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness).

The anticholinergic properties of Chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.
The effects of alcohol may be increased and therefore concurrent use should be avoided.
Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines
Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Keep out of the sight and reach of children.

4.5 Interactions with other medicinal products and other forms of interactions:
Concurrent use of Chlorpheniramine and hypnotics or anxiolytics may cause an increase in sedative effects, therefore medical advice should be sought before taking Chlorpheniramine concurrently with these medicines.
Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.
Additional information on special populations:
Not Applicable
Pediatric population:
Not Applicable

4.6 Fertility, pregnancy and lactation:
Pregnancy
There is no adequate data from the use of Chlorpheniramine Maleate in pregnant women. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essentially by a physician.
Lactation
Chlorpheniramine Maleate and other antihistamine may inhibit lactation and may be secreted in breast milk.
Not to be used during lactation unless considered essential by a physician.

4.7 Effects on ability to drive and use machines:
The anticholinergic properties of Chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment which can seriously hamper the patient's ability to drive and use machinery.

4.8 Undesirable effects:
Specific estimation of the frequency of adverse events for OTC products is inherently difficult (particularly numerator data). Adverse reactions which have been observed in clinical trials and which are considered to be common (occurring in 1% to <10% of subjects)

or very common (occurring in ≥ 10% of subjects) are listed below by MedDRA Sytem Organ Class. The frequency of other adverse reactions identified during post-marketing use is unknown.

Blood and lymphatic system disorders:
Unknown: haemolytic anaemia, blood dyscrasias

Immune system disorders:
Unknown: allergic reaction, angioedema, anaphylactic reactions

Metabolism and nutritional disorders:
Unknown: anorexia

Psychiatric disorders:
Unknown: confusion*, excitation*, irritability*, nightmares*, depression

Nervous system disorders*:
Very common: sedation, somnolence
Common: disturbance in attention, abnormal coordination, dizziness headache

Eye Disorders:
Common: blurred vision

Ear and labyrinth disorders:
Unknown: tinnitus

Cardiac disorders:
Unknown: palpitations, tachycardia, arrhythmias

Vascular disorders:
Unknown: Hypotension

Respiratory, thoracic and mediastinal disorders:
Unknown: thickening of bronchial secretions

Gastrointestinal disorders:
Common: nausea, dry mouth
Unknown: vomiting, abdominal pain, diarrhoea, dyspepsia

Hepatobiliary disorders:
Unknown: hepatitis, jaundice

Skin and subcutaneous disorders:
Unknown: exfoliative dermatitis, rash, urticaria, photosensitivity

Musculoskeletal and connective tissue disorders:
Unknown: muscle twitching, muscle weakness

Renal and urinary disorders:
Unknown: urinary retention

General disorders and administration site conditions:
Common: fatigue
Unknown: chest tightness

*Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).

Reporting of Suspected Adverse Reactions

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

4.9 Overdose and Treatment:

Symptoms and signs

The estimated lethal dose of Chlorpheniramine is 25 to 50mg per kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions, and fluid and electrolyte balance.

If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion).

Hypotension and arrhythmias should be treated vigorously; CNS convulsions may be treated with I.V. diazepam. Haemoperfusion may be used in severe cases.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Chlorpheniramine is a potent histamine H1, receptor antagonist.

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorpheniramine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of Chlorpheniramine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties:

Chlorpheniramine is readily absorbed from the GI tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life is estimated to be 12 – 15 hours.

There is significant plasma protein binding. The drug is largely inactivated in the liver and excreted as metabolites in the urine. Chlorpheniramine is metabolised to the monodesmethyl and didesmethyl derivative. About 22% of an oral dose is excreted unchanged in the urine. Only trace amounts have been found in the faeces.

5.3 Preclinical safety data:

None stated.

6. Pharmaceutical Particulars:

6.1 List of excipients

Rene-CPM tablets contain the following excipients:

Lactose, Maize starch, Dicalcium phosphate, Tartrazine supra, Sodium methyl paraben, Sodium propyl paraben, Sodium starch glycollate, Magnesium stearate.

6.2 Incompatibilities

None known

6.3 Shelf life

24Months

6.4 Special precaution for storage

Store in a cool, dry place below 30°C. Keep out of reach of children. Protect from light.

6.5 Nature and contents of container

Aluminium / transparent PVC blister strip of 10 tablets and 10 of such blister strip are packed in a unit box with pack insert.
1000 tablets packed in polythene bag and contained in HDPE container with leaflet.

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