CTD MODULE 1 ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION	
Product Name :	**RECODIN SYRUP** **(Chlorpheniramine Maleate 4mg and Codeine Phosphate 10mg)**

1.5 Product Information: RECODIN SYRUP

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: RECODIN SYRUP

Strength: Each 5 ml contain Chlorpheniramine Maleate BP 4mg and Codeine Phosphate BP 10 mg

Pharmaceutical form: Syrup

2. Qualitative and Quantitative composition:

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**			
		Each 5 ml contain Chlorpheniramine Maleate BP 4mg and Codeine Phosphate BP 10 mg			
		Quantity in mg per 5ml	**%**	**Quantity in Kg Per 1500L**	**%**
Contents of **RECODIN SYRUP**					
Chlorpheniramine Maleate	Active	4.000	0.31	1.200	0.31
Codeine Phosphate	Active	10.000	0.77	3.000	0.77
Carmellose sodium	Emulsifier	22.500	1.73	6.750	1.73
Sodium methyl paraben	Preservative	5.000	0.38	1.500	0.38
Sodium propyl paraben	Preservative	2.500	0.19	0.750	0.19
Sucrose	Sweetener	1000.000	76.90	300.000	76.90
Propylene glycol	Stabilizer	250.000	19.23	75.000	19.23
Sodium saccharin	Sweetener	5.000	0.38	1.500	0.38
Menthol	Flavour	1.000	0.08	0.300	0.08
Chocolate brown colour	Colour	0.350	0.03	0.105	0.03
Purified water	Solvent	Q.S 5ml	-	Q.S 1500L	-
Total	NA	1300.35	100.00	390.105	100.00

3. Pharmaceutical form: Syrup

4. Clinical particular's:

4.1 Therapeutic indication:

Recodin with Codeine syrup is specially formulated to provide relief from dry irritating cough and Flu associated with coughs (Painful coughs).

4.2 Posology and method of administration:

Posology

Recodin with codeine syrup is to be taken as follows or as instructed by the Physician.
Adults: take 5ml four times a day.
Children: Under 6 years: As directed by the Physician
6-12 years: 2.5ml three times a day.

Method of administration

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

4.3 Contraindication:

Recodin with codeine syrup should not be used by patients with hypersensitivity to any of the ingredients.

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:

Do not take codeine with other narcotic pain medications, sedatives, tranquilizers, muscle relaxers, or other medicines that can make you sleepy or slow your breathing. Avoid alcohol while taking Recodin with codeine syrup.

Side effects

Dizziness, Nausea, constipation, CNS stimulation, euphoria.

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

Recodin Syrup contain the following excipients:

Carmellose sodium, Sodium methyl paraben, Sodium propyl paraben, Sucrose, Propylene glycol, Sodium saccharin, Menthol, Chocolate brown colour, Purified water

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

100ml amber PET bottles and sealed with ROPP caps.

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