CTD MODULE 1 ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION	
Product Name :	**RENEGEL SUSPENSION (Dried Aluminium Hydroxide BP 120mg and Magnesium Trisilicate BP 250 mg)**

1.5 Product Information: RENEGEL SUSPENSION

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: RENEGEL SUSPENSION

Strength: Each 5 ml contains Dried Aluminium Hydroxide BP 120mg and Magnesium Trisilicate BP 250 mg

Pharmaceutical form: Suspension

2. Qualitative and Quantitative composition:

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**			
		Each 5 ml contains Dried Aluminium Hydroxide BP 120mg and Magnesium Trisilicate BP 250 mg			
		Quantity in mg per 5ml	**%**	**Quantity in Kg Per 500L Suspension**	**%**
Contents of **RENEGEL SUSPENSION**					
Dried aluminium hydroxide	Active	120.00	8.89	12.00	8.89
Magnesium trisilicate	Active	250.00	18.51	25.00	18.51
Sodium benzoate	Diluent	5.00	0.37	0.500	0.37
Sucrose	Sweetener	750.00	55.54	75.00	55.54
Citric acid anhydrous	Buffer	10.00	0.74	1.00	0.74
Sodium methyl paraben	Preservative	8.25	0.61	0.825	0.61
Sodium propyl paraben	Preservative	4.25	0.31	0.425	0.31
Guar gum	Suspending agent	22.500	1.67	2.250	1.67
Propylene glycol	Solvent	175.00	12.96	17.500	12.96
Menthol	Flavour	0.250	0.02	0.025	0.02
Peppermint oil	Flavour	0.005	0.37	0.500L	0.37
Tartrazine supra	Colouring agent	0.200	0.01	0.020	0.01
Purified water	Vehicle	Q.S 5ml	-	Q.S 500L	-
Total	NA	1345.45	100.00	135.045	100.00

3. Pharmaceutical form: Suspension

4. Clinical particular's:

4.1 Therapeutic indication:

Renegel is used in the relief of hyper acidity, gastritis, acid indication, gastroesophageal reflux and management of peptic ulcers.

4.2 Posology and method of administration:

Adults, elderly and children over 12 years of age:
10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required.

Children under 12 years of age:
Not recommended.

Method of Administration: Oral.

4.3 Contraindication:

Should not be used in patients who are severely debilitated or suffering from kidney failure.

4.4 Special warning and precaution for use:

Paediatric population
In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

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

Antacids inhibit the absorption of tetracyclines and vitamins and should not be taken concomitantly.
Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

Additional information on special populations:

Not Applicable

Pediatric population:

Not Applicable

4.6 Fertility, pregnancy and lactation:

For Renegel Suspension no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines:

None stated.

4.8 Undesirable effects:

Gastrointestinal side-effects are uncommon. This formulation minimises the problems of diarrhoea and constipation.

Frequency not known:

Abdominal pain.

Frequency very rare:

Hypermagnesemia. Observed after prolonged administration of magnesium hydroxide to patients with renal impairment.

4.9 Overdose and Treatment:

Serious symptoms are unlikely to follow overdosage.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Antacids either directly neutralize acidity, increasing the pH, or reversibly reduce or block the secretion of acid by gastric cells to reduce acidity in the stomach. When gastric hydrochloric acid reaches the nerves in the gastrointestinal mucosa, they signal pain to the central nervous system. This happens when these nerves are exposed. In addition to the reduction of gastric acidity, antacids also alter the profile of prostaglandins produced by gastroduodenal mucosa and this may promote mucosal healing and be related to its therapeutic effect.

5.2 Pharmacokinetic properties:

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

5.3 Preclinical safety data:

No relevant data

6. Pharmaceutical Particulars:

6.1 List of excipients

Dried Aluminium Hydroxide gel and Magnesium Trisilicate contain the following excipients:

Sodium benzoate, Sucrose, Citric acid anhydrous, Sodium methyl paraben, Sodium propyl paraben, Guar gum, Propylene glycol, Menthol, Peppermint oil, Tartrazine supra, Purified water.

6.2 Incompatibilities

None known

6.3 Shelf life

24Months

6.4 Special precaution for storage

Store in a cool, dry and dark place. Keep out of reach of children.

6.5 Nature and contents of container

100ml flavoured suspension filled in amber coloured glass 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