

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

<b>Product Name :</b>	<b>MINT-O-COOL TABLETS</b> <b>(Magnesium Trisilicate 250 mg and Dried Aluminium Hydroxide gel 120 mg)</b>
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**1.5 Product Information: MINT-O-COOL TABLETS**

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

**1. Name of the Medicinal Product: MINT-O-COOL TABLETS**

**Strength:** Each tablet contains Magnesium Trisilicate BP 250 mg, Dried Aluminium Hydroxide gel BP 120 mg

**Pharmaceutical form:** Tablet

**2. Qualitative and Quantitative composition:**

**Qualitative composition:**

Sr. No.	Ingredient	Specification	Uses
1.	Dried Aluminium Hydroxide gel	BP	Active
2.	Magnesium Trisilicate	BP	Active
3.	Maize starch (Mixing)	BP	Disintegrant
4.	Maize starch (Paste)	BP	Binder
5.	Sodium methyl paraben	BP	Preservative
6.	Sodium propyl paraben	BP	Preservative
7.	Sodium saccharin	BP	Sweetener
8.	Ponceau 4R supra	BP	Colour
9.	Sucrose	BP	Base
10.	Methylene Chloride	BP	Adhesive
11.	Menthol	BP	Flavour
12.	Peppermint oil	BP	Flavour
13.	Colloidal Silicon Dioxide	BP	Glidant
14.	Magnesium stearate	BP	Lubricant

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**Quantitative composition:**

Component and quality standard (and grade, if applicable)	Function	Strength (label claim)			
		Each tablet contains Magnesium Trisilicate BP 250 mg, Dried Aluminium Hydroxide gel BP 120 mg			
		Quantity in mg per tablet	%	Quantity in Kg Per 8,00,000 Tablets	%
<b>Contents of MINT-O-COOL TABLETS</b>					
Dried Aluminium Hydroxide gel	Active	120.00	20.18	97.920	20.18
Magnesium Trisilicate	Active	250.00	42.04	204.000	42.04
Maize starch (Mixing)	Disintegrant	86.460	14.54	69.168	14.54
Maize starch (Paste)	Binder	50.5	8.49	40.400	8.49
Sodium methyl paraben	Preservative	1.2	0.20	0.960	0.20
Sodium propyl paraben	Preservative	0.6	0.10	0.480	0.10
Sodium saccharin	Sweetener	2.00	0.34	1.600	0.34
Ponceau 4R supra	Colour	0.8	0.13	0.640	0.13
Sucrose	Base	70.500	11.86	56.400	11.86
Methylene Chloride	Adhesive	2.0µL	0.34	1.6L	0.34
Menthol	Flavour	0.04	0.01	0.032	0.01
Peppermint oil	Flavour	2.00	0.34	1.600	0.34
Colloidal Silicon Dioxide	Glidant	0.50	0.08	0.400	0.08
Magnesium stearate	Lubricant	8.00	1.35	6.400	1.35
Total	NA	594.6	100.00	481.6	100.00

**3. Pharmaceutical form:** Tablet

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**4. Clinical particular's:**

**4.1 Therapeutic indication:**

Mint-O-Cool 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:**

Mint-O-Cool is administered orally. Tablets should be chewed before being swallowed. Dose and frequency of administration depend on the acid secretory rate of the stomach, gastric emptying time and the disorder being treated. In fasting subjects antacids have duration of action of 20-60 minutes. However, if the drugs are administered 1 hour after meals, acid neutralizing effects may persist up to 3 hours. Antacids should be used for longer than 2 week periods only under the management of a physician and as part of a carefully planned therapeutic regimen.

**Method of Administration:** Oral.

**4.3 Contraindication:**

Contraindicated in patients hypersensitive to any of its components, in case of renal impairment, in patients with symptoms of appendicitis and hypophosphatemia.

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

Sodium bicarbonate is contra indicated and use of other sodium containing antacids should be restricted in patients on low sodium diets and in those with congestive heart failure, renal failure, edema or cirrhosis. Mint-O-Cool daily dosage should be used cautiously in patients with renal disease and only under the supervision of a physician.

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

Mint-O-Cool potentially may increase or decrease the rate and/or extend of absorption of concomitantly administered oral drugs by changing GI transit time or by binding or chelating the drug. Therefore medication should not be taken within 1-2 hours of Mint-O-Cool. Antacid induced increase in GI pH may affect the disintegration, dissolution, solubility or ionization of enteric coated preparations and weakly acidic or basic drugs.

**Additional information on special populations:**

Not Applicable

**Pediatric population:**

Not Applicable

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**4.6 Fertility, pregnancy and lactation:**

Animal studies are insufficient with respect to effects on pregnancy; embryonal/foetal development, parturition and postnatal development. The potential risk for humans is unknown. As there is no specific data for this product, it is recommended that Magnesium Trisilicate Mixture only be used in pregnancy on the advice of a doctor. Caution should be exercised when prescribing to pregnant women as this product contains sodium.

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

None

**4.8 Undesirable effects:**

Diarrhoea, belching due to liberated carbon dioxide, silica based renal stones reported on long term treatment.

**4.9 Overdose and Treatment:**

In case of over dosage of Mint-O-Cool, discontinue medication, treat symptomatically and institute supportive measures as required.

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**5. Pharmacological Properties:**

**5.1 Pharmacodynamic properties:**

Mint-O-Cool tablets composed of Magnesium Trisilicate and dried Aluminium hydroxide alerts the acidity of the stomach's juices by binding to excess acid. This decreases the acidity of the contents of the stomach which may in turn help to relieve the symptoms of ulcers, heartburn and dyspepsia.

**5.2 Pharmacokinetic properties:**

Magnesium chloride and hydrated silica gel are formed during the neutralization. About 5% of magnesium is absorbed and traces of liberated silica may be absorbed and excreted in the urine.

Any sodium hydrogen carbonate not neutralized in the stomach is absorbed and excreted as bicarbonate and sodium ions in the urine in the absence of a plasma deficit.

**5.3 Preclinical safety data:**

None known

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**6. Pharmaceutical Particulars:**

**6.1 List of excipients**

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

Maize starch (Mixing), Maize starch (Paste), Sodium methyl paraben, Sodium propyl paraben, Sodium saccharin, Ponceau 4R supra, Sucrose, Methylene Chloride, Menthol, Peppermint oil, Colloidal Silicon Dioxide and Magnesium stearate.

**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**

10 tablets are packed in Aluminium/ transparent PVC blister; such 10 blisters are packed in a unit carton along with literature insert.

1000 tablets packed in polythene bag and contained in HDPE Container with leaflet.

**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