

**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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**Pack Insert**

**MINT-O-COOL TABLETS**  
Compound Magnesium Trisilicate Tablets BP

**Composition**

Each uncoated tablet contains: Magnesium Trisilicate BP 250mg & Dried Aluminium Hydroxide BP 120 mg.

**Therapeutic class:** Antacid

**Clinical Pharmacology:**

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.

**Indication:**

Mint-O-Cool is used in the relief of hyperacidity, gastritis, acid indigestion, Gastroesophageal reflux and management of peptic ulcers.

**Dosage and 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.

**Contra indications:**

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

**Side effects:**

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

**Drug interactions:**

Mint-O-Cool potentially may increase or decrease the rate and/or extent 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.

**Special precautions and warnings:**

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.

**Over dosage:**

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

**Presentation:**

Blister pack of 10x10's and Jar of 1000's tablets

**Storage**

Store in a cool dry place, between 15°C - 30°C.

**MANUFACTURED BY:**  
RENE INDUSTRIES LIMITED  
Plot 680 Kamuli, Kireka  
P. O. Box 6034 Kampala Uganda



*A Milestone to Golden Health*

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**Label**

