

Summary of products characteristics (SmPC):

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

2. Qualitative and Quantitative composition:

Each tablet contains Magnesium Trisilicate BP 250 mg, Dried Aluminium Hydroxide gel BP 120 mg
For the full list of excipients, See section 6.1

3. Pharmaceutical form: Tablet

A pink coloured round flat tablets with break line on one side and plain on other side

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 2week 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

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.

Important information about some of the ingredients of this medicine: Contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Antacid

ATC Code: A02AD01 (Magnesium Trisilicate), A02AB01 (Aluminium Hydroxide)

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

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

Do not store above 30°C

Protect from light

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.

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