For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

PACKAGE INSERT

RANTAC MPS SUSPENSION

GENERIC NAME

Magaldrate and Simethicone Oral Suspension

COMPOSITION

Each 5mL contains	
Magaldrate IP	400mg
Activated Polydimethylsiloxane IP	20mg
In a Flvaoured Sugar-free Base	q.s

DOSAGE FORM

Oral Suspension

INDICATIONS

• Gastritis and dyspepsia
• Gastric and Duodenal ulcers
• Drug induced gastric irritation
• Gastro-Oesophageal Reflux
• Heart burn
• Upset stomach characterized by pain, burning, nausea and flatulence

DOSAGE AND METHOD OF ADMINISTRATION

10-20 ml three or four times a day, on empty stomach, or as directed by a doctor.

Method of use
• It is best to take them with food as the buffering effect in the stomach lasts for 2 to 3 hours.
• If symptoms occur at night, then they are usually administered before retiring.
• However, it is more important not to eat within 2 hours of sleep as eating often promotes reflux of acid into the esophagus.

Duration of use
It can be used indefinitely if they are only taken occasionally. However, when it is necessary several times a day, medical attention or use of H2 blocker or PPIs may be required.

USE IN SPECIAL POPULATIONS

Pregnancy and Lactation
FDC of Magaldrate and Simethicone Suspension has not been formally assigned to a pregnancy category by the FDA. Animal studies have not been reported. There are no controlled data in human pregnancy. Magaldrate and Simethicone Suspension is only recommended for use during pregnancy when benefit outweighs risk. There are no data on the excretion of magaldrate-simethicone into human milk. Some aluminium or magnesium

containing antacids may pass into breast milk. However, these medicines have not been reported to cause problems in nursing babies.

Renal impairment-
FDC of Magaldrate and Simethicone is contraindicated in patients with renal impairment.

Liver impairment-
No data found.

Elderly
Aluminium containing antacids should not be used by elderly persons with the bone problems or with Alzheimer's disease. The aluminum may cause their condition to get worse.

Pediatric Use
Not recommended in children under 6 years of age unless, directed by physician.

CONTRAINDICATIONS

FDC of Magaldrate and Simethicone is contraindicated in

- Hypersensitivity to any of the ingredient.
- Patients with severe renal dysfunction, hypophosphatemia, nausea, vomiting, severe abdominal pain, acute surgical abdomen impaction and/or an intestinal obstruction.
- Patients taking citrate salts (found in some calcium supplements, antacids and laxatives)
- Patients with impaired renal functions.
- Patients with known hypersensitivity to magnesium and aluminium.

WARNINGS & PRECAUTIONS

Magaldrate and Simethicone Suspension should be used with caution in patients with renal impairment to avoid hypomagnesemia and toxicity or in patients with recent massive upper GI hemorrhage. Care should be taken in hypophosphatemia.

DRUG INTERACTIONS

Antacids do interact with or prevent the absorption of many medications. As a general rule it is best to separate antacid use and any other medication by at least 1 hour. When antacids are only taken occasionally, this seldom presents a serious problem.

Magaldrate and Simethicone Suspension used concurrently with oral tetracyclines, digoxin, oral iron preparations, anticholinergic drugs, barbiturates, quinines, warfarin, vitamins, H2-receptor antagonists, oral isoniazid, sucaralfate, sodium fluoride, ketoconazole, phenytoin, phenothiazines and methenamine may reduce the absorption of these agents.
Magaldrate and Simethicone Suspension may cause reduced bio-availability or slower absorption of a number of drugs including propranolol, isoniazid, prednisolone and naproxen.
Levothyroxine may bind to Simethicone. Absorption of levothyroxine may be impaired if simeticone is given concurrently to infants treated for thyroid disorders.

UNDESIRABLE EFFECTS

Central nervous system: Encephalopathy

Gastrointestinal: Constipation, chalky taste, stomach cramps, fecal impaction, diarrhea, nausea, vomiting, discoloration of feces (white speckles), rebound hyperacidity, loss of appetite.

Endocrine & metabolic: Hypophosphatemia, hypermagnesemia, milk-alkali syndrome
Neuromuscular & metabolic: Osteomalacia
Miscellaneous: Aluminum intoxication, muscle weakness
Severe but rare side effects include allergic reactions (rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue).

OVERDOSE

Symptoms of overdose may include dizziness, fatigue, weakness, severe nausea and vomiting, loss of appetite, drowsiness, slow or shallow breathing, or loss of consciousness.
Large dose can cause obstruction. Do not use maximum dose of this product for more than two weeks, except under advice and supervision of a physician.

PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES

Pharmacodynamics

Magaldrate:
Magaldrate rapidly neutralizes acid and has sufficient buffering capacity to provide sustained activity. It reduces gastric and duodenal irritation and also binds bile salt and pepsin. It helps to relieve symptoms of excessive stomach acidity in patients with indigestion, heartburn, gastroesophageal reflex disorder (GERD), or stomach or duodenal ulcers.

Simethicone:
Simethicone is an anti-gas (anti-flatulence) medication. It acts in the stomach and intestines to change the surface tension of gas bubbles, enabling smaller bubbles to join together into bigger bubbles. In this way it is believed that gas can be eliminated more easily by belching or passing flatus. Simethicone is not absorbed by the body into the bloodstream, and is therefore considered relatively safe

Physiologically the active ingredient is a chemically inert, non-systemic gastric defoaming agent that works by altering the elasticity of interfaces of mucus-embedded bubbles in the gastrointestinal tract. The gas bubbles are thus broken down or coalesced and in this form gas is more easily eliminated through eructation or passing flatus.

Pharmacokinetics

Magaldrate:
Magaldrate reacts with acid in stages. The hydroxymagnesium is relatively rapidly converted to magnesium ion and the aluminate to hydrated aluminium hydroxide; the aluminium hydroxide then reacts more slowly to give a sustained antacid effect.
Anywhere from 15% to 30% of the magnesium ion is absorbed; however, in the normal person, magnesium ion is rapidly excreted by the kidney.
The reaction of magnesium hydroxide with hydrochloric acid produces magnesium chloride. Most of the magnesium chloride is converted to magnesium carbonate in the intestine and is thus excreted. In the stomach, aluminium hydroxide neutralizes hydrochloric acid. After the aluminium chloride enters the intestine some of the chloride is reabsorbed, the insoluble aluminium hydroxide and aluminium phosphate are formed.

Simethicone:
Simethicone is physiologically inert; it does not appear to be absorbed from the GI tract or to interfere with gastric secretion or absorption of nutrients. Following oral administration, the drug is excreted unchanged in feces.

INCOMPATIBILITIES

Not applicable.

PACKAGING INFORMATION

Pet bottle of 170 mL

STORAGE AND HANDLING INSTRUCTIONS

Store in a cool and dry place. Protect from light.

MANUFACTURED AND MARKETED BY

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