
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Reme-D (Milk of Magnesia) Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Magnesium Hydroxide % w/w eq to 8.23 % w/v

3. PHARMACEUTICAL FORM

White opaque more or less viscous suspension having a taste and odour of peppermint with mint flavour and from which varying proportions of water usually separate on standing.

4. Clinical particulars

4.1 Therapeutic indications

Milk of Magnesia is indicated as an antacid for the symptomatic relief of stomach discomfort, indigestion, hyperacidity, heartburn and flatulence; and as a laxative for constipation.

4.2 Posology and method of

administration Use as Laxative:

Adults and children over 12 year: 2-4 teaspoonfuls in glass of water taken before bedtime.

Children 1-5 years: half teaspoon (2.5ml)
twice daily. 6-12 years: one teaspoonful
(5ml) twice daily.

Use as Antacid:

Adults and children over 12 year: 1-2 teaspoonfuls (5ml-10ml) in water taken after meals 2-3 times daily.

Children 1-5 years: half teaspoon (2.5ml) twice daily. 6-12 years: one teaspoonful (5ml) twice daily.

For Infant Feeding:

Addition of one tablespoonful in 500ml of cow's milk or half tablespoon in 500ml of powdered baby milk helps make milk more digestible and prevents constipation.

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1. Acute gastrointestinal conditions.

4.4 Special warnings and precautions for use

Osmotic laxatives act by increasing osmotic pressure, thereby promoting retention of fluid within the bowel, which can in turn affect water / electrolyte balance. Adequate fluid intake should be maintained during use. If diarrhoea occurs especially in children or the elderly, discontinue use immediately. In case of renal impairment a doctor should be consulted as hypermagnesaemia may occur. If symptoms persist or worsen, a doctor or pharmacist should be consulted.

Do not use as a laxative for more than three consecutive days, or as an antacid for more than fourteen consecutive days.

If a laxative dose is needed every day or if there is a persistent abdominal pain further medical advice should be sought.

Users taking medicines either physician prescribed or self-prescribed should consult a doctor or pharmacist before use.

Keep out of the reach and sight of children.

Paediatric population

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

This medicinal product contains less than 1 mmol sodium (23 mg) per 45ml, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Magnesium hydroxide may interfere locally with the absorption of other drugs taken orally by increasing gastric pH.

Magnesium salts reduce the absorption of a number of other drugs taken concomitantly. These include:

Interaction	Recommendation
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<u>Antibacterials and antifungals</u> (e.g. cefpodoxime, itraconazole, tetracyclines, ketoconazole and the quinolone group of antibacterials [†])	Antacids reduce the absorption of some antibacterials and antifungals. Administration should be separated by at least 2 hours. †quinolone antibacterials should be taken at least 2 hours before and not less than 4 to 6 hours after magnesium containing salts.
<u>Antivirals</u> (e.g. atazanavir, tipranavir, rilpivirine [#])	Antacids reduce the absorption of some antivirals. Administration should be separated by at least 2 hours.

	[#] Antacids should only be taken at least 2 hours before and 4 hour after rilpivirine .
<u>Antihistamines</u> (fexofenadine)	Antacids reduce the absorption of fexofenadine. Administration should be separated by 2 hours.
<u>Bisphosphonates</u> (such as alendronate, clodronate, risedronate, ibandronic acid)	Oral magnesium decreases the absorption of bisphosphonates. Alendronic acid should be taken at least 30 minutes before magnesium. Oral magnesium should be avoided for at least 6 hours before and 1 hour after ibandronic acid. Oral magnesium should be avoided for at least 2 hours with risedronate and sodium clodronate.
<u>Corticosteroids</u> (deflazacort, dexamethasone)	Oral magnesium reduces the absorption of deflazacort and dexamethasone and it should be administered 2 hours before or after these medicinal products.
<u>Digoxin</u>	Antacids reduce the absorption of digoxin. The administration of digoxin should be separated by 2 hours.
<u>Dipyridamole</u>	Antacids possibly reduce the absorption of dipyridamole; concomitant administration

	should be avoided.
<u>Antiepileptics</u> (gabapentin and phenytoin)	Antacids reduce absorption of some antiepileptics (e.g. gabapentin, phenytoin). Antiepileptics should be taken 2 hours after antacids.
<u>Levothyroxine</u>	Antacids possibly reduce absorption of levothyroxine. The administration of levothyroxine should be separated by at least 4 hours.
<u>Mycophenolate</u>	Antacids decrease exposure to mycophenolate; concomitant administration should be avoided.
<u>Iron preparations</u>	Antacids decrease the absorption of oral iron. Iron should be taken 1 hour before or 2 hours after antacids.
<u>Lipid regulating medicinal products</u> (rosuvastatin)	Antacids decrease the absorption of rosuvastatin. The administration should be separated by 2 hours.
<u>Antipsychotics</u> (e.g. sulpiride, phenothiazines, chlorpromazine)	Antacids reduce the absorption of some antipsychotics (e.g. sulpiride, phenothiazines, chlorpromazine). The administration should be separated by 2 hours.

<u>Antimalarials</u> (chloroquine, hydroxychloroquine, proguanil)	Antacids reduce absorption of chloroquine, hydroxychloroquine (administration should be separated by at least 4 hours). Oral magnesium salts (as magnesium trisilicate) reduce absorption of proguanil (administration should be separated by at least 2 hours).
<u>Penicillamine</u>	Antacids reduce absorption of Penicillamine. Administration should be separated by 2 hours.

Milk of Magnesia may interact with dicoumerol and cimetidine.
Magnesium hydroxide may increase the absorption of ibuprofen.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

Co-administration of sodium polystyrene sulphonate results in a relative excess of bicarbonate ions, which are absorbed, and may lead to metabolic alkylolysis.

4.6 Fertility, pregnancy, and lactation

Pregnancy

For Magnesium hydroxide 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.

Breastfeeding

Magnesium crosses the placenta and is excreted in small amounts in breast milk. Use during pregnancy and lactation should be avoided unless on the advice of a doctor.

Fertility

There are no data available regarding the influence of Milk of Magnesia on fertility.

4.7 Effects on ability to drive and use machines

Magnesium hydroxide is unlikely to cause any effects on the ability to drive and use machines.

4.8 Undesirable effects

In patients with impaired renal function there may be sufficient accumulation of magnesium to produce toxic effects.

Body System	Undesirable effect	Frequency
Gastrointestinal disorders	Abdominal pain (including colic), Diarrhoea	Unknown
Metabolism and nutrition disorders	Hypermagnesemia – observed after prolonged administration of magnesium hydroxide to patients with renal impairment	Very rare

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)
<https://pv.pharmacyboardkenya.org>

4.9 Overdose

Symptoms

Symptoms of overdose include gastrointestinal irritation and watery diarrhoea. Magnesium poisoning may produce hypermagnesaemia, symptoms of which include nausea, vomiting, flushing, thirst, hypotension, drowsiness, confusion, loss of tendon reflexes, muscle weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest.

Treatment

Treatment consists of the intravenous administration of calcium gluconate injection 10% in a dose of 10-20ml to counteract respiratory depression or heart block. If renal function is normal, adequate fluids should be given to assist removal of magnesium from the body. Dialysis

may be necessary in patients with renal impairment or severe hypermagnesaemia.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Magnesium Antacids compounds

ATC code: A02AA

Mechanism of action

Magnesium hydroxide is practically insoluble in water and solution is not effected until the hydroxide reacts with hydrochloric acid in the stomach to form magnesium chloride. Its neutralising action is almost equal to that of sodium bicarbonate. When the dose is in excess of that required to neutralise the acid the intragastric pH may reach pH 8 or 9. Acid rebound following magnesium hydroxide is clinically insignificant.

Magnesium hydroxide has an indirect cathartic effect resulting from water retention in the intestinal lumen

5.2 Pharmacokinetic properties

Magnesium hydroxide exerts its antacid therapeutic effect rapidly within the gastro-intestinal tract following oral administration and this action is therefore independent of pharmacokinetic properties. Following oral administration, about one third to half the magnesium is absorbed very slowly from the small intestine. Magnesium salts are excreted mainly in the urine with small amounts in the faeces and saliva.

5.3 Preclinical safety data

Magnesium hydroxide has been used for many years and no further data are presented in this section.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium Saccharine
- Peppermint Oil
- Mineral Oil
- Dry Chlorine

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years (36 months)

6.4 Special precautions for storage

Store below 30°

C. Do not

Freeze.

Protect from light and heat.

Keep out of the reach of children. Do not use after expiry date mentioned on the package. To be sold on the prescription of a registered Medical practitioner only.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Reme-D is available in 114 ml amber glass bottle in a printed unit carton along with package insert.

6.6 Special precautions for disposal <and other handling>

No special requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorization Holder (MAH):

Company name: Globe Pharmacy Limited.
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Manufacturing Site:

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8. MARKETING AUTHORIZATION NUMBER

11957

**9. DATE OF FIRST REGISTRATION / RENEWAL OF THE
REGISTRATION**

September 23, 2010

10. DATE OF REVISION OF THE TEXT

16/06/2026