Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Milk of Magnesia Traditional Mint Flavoured Liquid, 415 mg/5 ml, oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium Hydroxide 415mg per 5ml suspension.

Excipient (s) with known effect:
Sodium (as sodium bicarbonate and sodium saccharin (E954)): 0.15 mg / ml
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

White, opaque, slightly viscous suspension with an odour of peppermint and a taste of peppermint.

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.
As a laxative in occasional constipation.

4.2 Posology and method of administration

Use a 5 ml spoon or the dosing cup provided.

Shake well before use.

Take doses with water if required.

Do not exceed the stated dose.

As an antacid for stomach upsets and indigestion:

Adults (including the elderly) and children aged 12 years and over:

5-10 ml (one or two 5 ml spoonfuls or fill the dosing cup to the first or second line). Repeat as necessary to a maximum daily dose of 60 ml (12, 5ml spoonfuls) in any 24 hours.

Children aged 6-11 years:

5 ml (one spoonful or first line in dosing cup). Repeat as necessary to a maximum daily dose of 30 ml in any24 hours.

As a laxative:
Adults (including the elderly) and children aged 12 years and older:

30-45 ml at bedtime. Repeat nightly, reducing dose each night until constipation is relieved. Do not use for more than 3 consecutive days.

Children aged 2 - 11 years:

5-10 ml at bedtime. Repeat nightly reducing the dose until constipation is relieved. Do not use for more than 3 consecutive days.

Not to be given to children except on medical advice.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

In case of intestinal obstruction, faecal impaction and appendicitis.

4.4 Special warnings and precautions for use

Keep out of sight and reach of children.
If diarrhoea occurs especially in children or the elderly, discontinue use immediately. Adequate fluid intake should be maintained during use
If symptoms persist or worsen, consult your doctor. Prolonged continuous use is not recommended.
In case of renal impairment a doctor should be consulted prior to use as hypermagnesaemia may occur. Users taking medications either physician or self-prescribed should consult a doctor before use.
Osmotic laxatives can cause dehydration and hydroelectrolytic balance disorders.
If a laxative dose is needed every day or if there is a persistent abdominal pain further medical advice should be sought. Do not use as a laxative for more than three consecutive days, or as an antacid for more than fourteen consecutive days.
Milk of Magnesia contains sodium. For patients on a controlled sodium diet this should be taken into consideration.
Not to be given to children except on medical advice.
Paediatric population
In young children, the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

4.5 Interaction with other medicinal products and other forms of interactions

Magnesium hydroxide may interfere locally with the absorption of other drugs taken orally by increasing gastric pH. This can be avoided by giving other drugs 2-3 hours before the administration of magnesium hydroxide on the advice of a doctor.

Magnesium salts reduce the absorption of a number of other drugs taken concomitantly. These include :
-ACE inhibitors (captopril, enalapril, fosinapril);
-beta-blockers (propanolol, atenolol),·
-antibacterials and antifungals (azithromycin, cefaclor, cefpodoxime, isoniazid, itraconazole capsules nitrofurantoin, rifampicin, tetracyclines, ketoconazole capsules and the quinolone group of antibacterials);
-antivirals (atazanavir, fosamprenavir, tipranavir, delavirdine, rilpivirine);
-antihistamines (fexofenadine);
-bisphosphonates (alendronate, tiludronate, clodronate, risedronate, etidronate);
-corticosteroids (deflazacort, prednisone, prednisolone, dexamethasone);
-digoxin;
-dipyridamole;
-antiepileptics (gabapentin and phenytoin);
-ulcer healing drugs (lansoprazole);
-levothyroxine;
-mycophenolate;
-iron preparations;
-lipid regulating drugs (rosuvastatin);
-antipsychotics (sulpiride, phenothiazines, chlorpromazine);
-antimalarials (chloroquine, hydrochloroquine, proguanil);
-penicillamine.

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 alkalosis.

4.6 Fertility, pregnancy and lactation

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

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.
Lactation
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.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse reactions reported from extensive post-marketing experience are tabulated below by System Organ Class and frequency. The following convention has been utilised for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).

System Organ class	Undesirable effect	Frequency
Gastro-intestinal disorders	Abdominal pain (colic), diarrhoea	Not known

Diarrhoea may occur which is dose related.
In patients with impaired renal function there may be sufficient accumulation of magnesium to produce toxic effects (see Overdose).

Body System	Undesirable effect	Frequency
Gastorintestinal disorders	Abdominal pain	Not known
Metabolism and nutritional disorders	Hypermagnesemia – observed after prolonged administration of magnesium hydroxide to patients with renal impairment	Very rare

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms and Signs

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

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 hydrogen carbonate
Oil of peppermint
Glycerol
Sodium saccharin
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.
Use within 6 months of opening.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

Blue HDPE bottles with white HDPE screw turn tamper evident inner cap and external click on dosing cap. Pack size 100ml and 200ml.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

6.6 Special precautions for disposal

Shake bottle well before use.

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 August 1992
Date of last renewal: 20 August 2007

10 DATE OF REVISION OF THE TEXT

November 2019