# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Phillips' Milk of Magnesia

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium Hydroxide BP 415 mg per 5 ml suspension.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral Suspension.

## 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 a 5 ml spoon or the dosing cup provided.
Doses may be taken with milk or water if desired.
Do not exceed the stated dose.

**As an antacid:**

Adults: 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 of 60 ml in 24 hours.

Children aged 3-12 years: 5 ml (one spoonful or first line in dosing cup). Repeat as necessary to a maximum of 30 ml in 24 hours.

**As a laxative:**

Adults: 30-45 ml at bedtime. Repeat nightly, reducing dose each night until constipation is relieved.

Children aged over 3 years: 5-10 ml at bedtime.

Children aged under 3 years: to be given only on the advice of a doctor.

Elderly: As adult dose.

## 4.3 Contraindications

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

## 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** |
|---|---|

| **Interaction** | **Recommendation** |
|---|---|
| Antibacterials and antifungals<br>(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.<br><br>†**quinolone antibacterials** should be taken at least 2 hours before and not less than 4 to 6 hours after magnesium containing salts. |
| Antivirals<br>(e.g. atazanavir, tipranavir, rilpivirine#) | Antacids reduce the absorption of some antivirals. Administration should be separated by at least 2 hours.<br><br>#Antacids should only be taken at least 2 hours before and 4 hour after **rilpivirine**. |
| Antihistamines<br>(fexofenadine) | Antacids reduce the absorption of fexofenadine. Administration should be separated by 2 hours. |
| Bisphosphonates<br>(such as alendronate, clodronate, risedronate, ibandronic acid) | Oral magnesium decreases the absorption of bisphosphonates.<br><br>Alendronic acid should be taken at least 30 minutes before magnesium.<br>Oral magnesium should be avoided for at least 6 hours before and 1 hour after ibandronic acid.<br>Oral magnesium should be avoided for at least 2 hours with risedronate and sodium clodronate. |
| Corticosteroids<br>(deflazacort, dexamethasone) | Oral magnesium reduces the absorption of deflazacort and dexamethasone and it should be administered 2 hours before or after these medicinal products. |
| Digoxin | Antacids reduce the absorption of digoxin. The administration of digoxin should be separated by 2 hours. |
| Dipyridamole | Antacids possibly reduce the absorption of dipyridamole; concomitant administration should be avoided. |
| Antiepileptics (gabapentin and phenytoin) | Antacids reduce absorption of some antiepileptics (e.g. gabapentin, phenytoin). Antiepileptics should be taken 2 hours after antacids. |
| Levothyroxine | Antacids possibly reduce absorption of levothyroxine. The administration of levothyroxine should be separated by at least 4 hours. |
| Mycophenolate | Antacids decrease exposure to mycophenolate; concomitant administration should be avoided. |
| Iron preparations | Antacids decrease the absorption of oral iron. |

| Interaction | Recommendation |
|---|---|
| | Iron should be taken 1 hour before or 2 hours after antacids. |
| Lipid regulating medicinal products (rosuvastatin) | Antacids decrease the absorption of rosuvastatin. The administration should be separated by 2 hours. |
| Antipsychotics (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. |
| Antimalarials (chloroquine, hydroxychloroquine, proguanil) | Antacids reduce absorption of chloroquine, hydroxychloroquine (administration should be separated by at least 4 hours).<br>Oral magnesium salts (as magnesium trisilicate) reduce absorption of proguanil (administration should be separated by at least 2 hours). |
| Penicillamine | 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 alkylosis.

## 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 (see section 4.9).

| Body System | Undesirable effect | Frequency |
|---|---|---|
| Gastrointestinal disorders | Abdominal pain (including colic)<br>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
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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

## 4.9 Overdose

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,
Purified Water

### 6.2 Incompatibilities

None.

### 6.3 Shelf life

36 months;
After opening: 6 months.

### 6.4 Special precautions for storage

Store below 25 °C. Do not freeze.
Shake bottle well before use

### 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, 190ml and 200ml.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

Omega Pharma Ltd.
Wrafton,
Braunton,
Devon,
EX33 2DL,
UK

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 02855/0072

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd March 1999

## 10 DATE OF REVISION OF THE TEXT

09/12/2025