PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

IMPILO MILK OF MAGNESIA, 425 mg/5 ml, Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Magnesium hydroxide 425 mg

Preservative: Sodium benzoate 0,12 % *m/v*

Sugar free

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Suspension

A white suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Where the use of an antacid is indicated. For the relief of occasional constipation.

4.2 Posology and method of administration

Posology

SHAKE BOTTLE BEFORE USE

ANTACID

Adults: 5 – 10 ml (one or two medicine measures)

Children 3 – 10 years: 2,5 ml (half a medicine measure)

Not more than three to four times per 24 hour period.

LAXATIVE

When used as a laxative, the medicine should be followed with sufficient water to prevent nett loss of body water. Take as a single dose, or as directed by a doctor.

This product generally produces bowel movement in half to six hours.

Adults: 20 – 40 ml (four to eight medicine measures)

Children 2 – 6 years: 5 – 10 ml (one to two medicine measures)

6 – 12 years: 10 – 20 ml (two to four medicine measures)

The dosage recommended above should not be exceeded in a 24 hour period.

Do not use the maximum daily dosage of this product for more than one week except under the advice and supervision of a doctor.

Method of administration

Oral administration only.

4.3 Contraindications

- Not to be taken by patients with severe renal failure or dehydration.
- Must not be given to patients who are sensitive to any of the ingredients.

4.4 Special warnings and precautions for use

Use with caution in patients with impaired renal function and debility.

Not to be taken by persons suffering from diarrhoea, abdominal pain, nausea or vomiting, unless directed by a doctor. If a sudden change in bowel habits is noticed, that persists over a period of 2 weeks, consult a doctor before using the laxative. Rectal bleeding or failure to have a bowel movement after the use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.

Excipient warnings:

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'. This medicine contains 6,0 mg sodium benzoate in each 5 ml dose, which is equivalent to 0,12 % *m/v.*

Increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

4.5 Interaction with other medicines and other forms of interaction

This preparation may interfere with the absorption of other medicines if taken concomitantly by increasing gastric pH. This can be avoided by giving other medicines 2-3 hours before the administration of magnesium hydroxide.

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

- ACE inhibitors (captopril, enalapril, fosinapril);
- beta-blockers (propranolol, atenolol);
- antibacterials and antifungals (azithromycin, cefaclor, cefpodoxime, isoniazid, itraconazole, 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 (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.

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.

4.6 Fertility pregnancy and lactation

The safety of this preparation in pregnancy and lactation has not been established.

No fertility data available.

4.7 Effects on ability to drive and use machines

No effects are expected on the ability to drive or use machines.

4.8 Undesirable effects

MedDRA system organ class	Frequency	Adverse reactions
Metabolism and nutrition disorders	Less frequent	Hypermagnesaemia. Observed after prolonged administration of magnesium hydroxide to patients with renal impairment.
Gastrointestinal disorders	Frequency unknown	Abdominal pain, diarrhoea (a dose-dependent effect), colic.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Overdosage may be characterised by excessive purging. If symptoms of hypermagnesaemia (such as flushing of the skin, thirst, hypotension, drowsiness, confusion, loss of tendon reflexes, muscle weakness, respiratory depression, cardiac dysrhythmias, coma and cardiac arrest) are observed, consult a doctor. Respiratory depression or heart block can be counteracted with intravenous administration of calcium gluconate injection 10 % in a dose of 10 - 20 ml. 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 groups: Medicines for acid related disorders / Osmotically acting laxatives

ATC codes: A02AA04 / A06AD02

Magnesium hydroxide has an acid neutralising capacity and diminishes the activity of pepsin in gastric secretion. In large doses, it acts as a saline laxative by osmotic action.

5.2 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.

PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Citric acid monohydrate
- Purified water
- Sodium benzoate (Preservative)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C in a cool place. Do not freeze.

Keep bottle tightly closed.

6.5 Nature and contents of container

100 ml PVC bottles with white plastic caps.

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION:

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8. REGISTRATION NUMBER

E764

9. DATE OF FIRST AUTHORISATION

29 September 1994

10. DATE OF REVISION OF THE TEXT

21 August 2024