PROFESSIONAL INFORMATION
QUMA ANTACID

SCHEDULING STATUS

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1 NAME OF THE MEDICINE
QUMA ANTACID, 106 mg/5 ml, Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 ml contains:
Magnesium hydroxide 106 mg
Sodium benzoate (preservative) 0,1 % *m/v*
Sugar free
For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM
Suspension
A pink suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Where the use of an antacid is indicated.

4.2 Posology and method of administration
Posology
SHAKE BOTTLE BEFORE USE

Children under 1 month:	2,5 ml (half a medicine measure) per dose
1 to 6 months:	3,5 ml (three-quarter of a medicine measure) per dose
6 months to 1 year:	5,0 ml (one medicine measure) per dose
1 to 3 years:	7,5 ml (one and a half medicine measure) per dose
3 to 5 years:	10,0 ml (two medicine measures) per dose

Not more than three to four times per 24 hour period.
Do not give to babies with a body mass of less than 2,5 kg.
Method of administration
Oral administration only.

4.3 Contraindications
QUMA ANTACID is contraindicated in:
- Patients with impaired renal function, debility, or dehydration.
- Hypersensitivity to magnesium hydroxide or any of the ingredients listed in Section 6.1.

4.4 Special warnings and precautions for use
Not to be given to 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 medicine. Do not exceed the maximum recommended dose in any 24 hour period.
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 5,25 mg sodium benzoate in each 5 ml dose, which is equivalent to 0,1 % *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).
This medicine contains 53,91 mg of alcohol (ethanol) in each 5 ml, which is equivalent to 1,08 % *m/v.* The amount in 5 ml of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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 iimpairment.
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 arrhythmias, 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 group: Medicines for acid related disorders - Antacids
ATC code: A02AA04
Magnesium hydroxide has a high 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
- Caraway oil
- Citric acid monohydrate
- Ethanol 96 %
- Purified water
- Raspberry food colour (Permicol Raspberry Red H1277) CI-14720
- 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 and 200 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
E840

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22 July 1994

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02 September 2024