SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ALUMAG D 5 mg/400 mg/200 mg per 10 ml suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of the suspension contains:

Dicyclomine hydrochloride	5 mg
Compressed aluminium hydroxide gel equivalent to:	
Dried aluminium hydroxide	400 mg
Light magnesium oxide	200 mg

Preservatives:	
Nipastat	0,2 % *m/v*
Chloroform	0,2 % *v/v*
Benzyl alcohol	0,3 % *v/v*

Contains sugar: Sorbitol 910 mg

Contains sweetener: Sodium cyclamate 30 mg, saccharin sodium 3,25 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension.

A white homogenous suspension with slight peppermint flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ALUMAG D is indicated as an antacid.

4.2 Posology and method of administration

Posology

Adults:	Two to four medicine measures (10 - 20 ml) three to four times daily.
Children over 2 years of age:	One to two medicine measures (5 - 10 ml) three to four times daily.

Method of administration

For oral administration.

4.3 Contraindications

- Hypersensitivity to dicyclomine hydrochloride, dried aluminium hydroxide, light magnesium oxide or to any of the excipients listed in section 6.1.
- Prostatic enlargement.
- Paralytic ileus or pyloric stenosis where its use may lead to obstruction.
- Severe ulcerative colitis.
- Myasthenia gravis.
- Glaucoma.
- Renal failure.
- Obstructive uropathy.
- Thyrotoxicosis.
- Cardiac failure.

- Should not be given to children under two years.

4.4 Special warnings and precautions for use

ALUMAG D should be used with caution in conditions characterised by tachycardia.

Hypersensitivity may appear as conjunctivitis or a skin rash.

Preparations containing dicyclomine should be used with caution in elderly men.

Mucosal irritation and absorption of magnesium may occur if there is gastrointestinal atony or obstruction.

5 - 10 % of magnesium is absorbed, and retention in patients with impaired renal function may lead to neurological, neuromuscular and cardiovascular impairment. The urine of normal persons may become alkaline which decreases excretion of medicines that are weak bases.

Use with care in patients with hiatal hernia associated with reflux oesophagitis because anticholinergic medicines may aggravate the condition.

Excipients with known effect

ALUMAG D contains nipastat, a mixture of parahydroxybenzoate esters. It may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm.

ALUMAG D contains benzyl alcohol, 0,03 ml/10 ml, equivalent to 0,3 % *v/v*. Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. Do not use for more than a week in young children (between 2 and 3 years old), unless advised by your doctor or pharmacist.

High volumes of benzyl alcohol should be used with caution, especially in patients with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

ALUMAG D contains sorbitol 70 % equivalent to 910 mg/10 ml sorbitol. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.
Patients with hereditary fructose intolerance (HFI) should not take/be given ALUMAG D.
Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

ALUMAG D contains ethanol 0,34 % *v/v*. The amount in 10 ml of ALUMAG D is equivalent to less than 0,17 ml beer or 0,43 ml wine. The small amount of alcohol in ALUMAG D will not have any noticeable effects.
ALUMAG D contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicines and other forms of interaction

The effects of ALUMAG D may be enhanced by other medicines with anticholinergic properties such as antihistamines, amantadine, butyrophenones, phenothiazines and tricyclic antidepressants.
Magnesium may interfere with the absorption of tetracyclines.

Aluminium hydroxide absorbs phosphates and excessive doses or normal doses with a low phosphate diet may lead to phosphate depletion with renal rickets or osteomalacia.

It reduces the absorption of medicines such as tetracyclines, vitamins, warfarin, quinidine, quinine, anticholinergic medicines, barbiturates and digoxin.

The content of sorbitol in medicines for oral use may affect the bioavailability of other medicines for oral use administered concomitantly.

4.6 Pregnancy and lactation

The safety of ALUMAG D in pregnancy and lactation has not been established.

ALUMAG D contains benzyl alcohol. Large amounts of benzyl alcohol can build-up in the body and may cause metabolic acidosis.

4.7 Effects on ability to drive and use machines

Since adverse reactions such as fatigue, sedation, dizziness and blurred vision have been reported in patients receiving ALUMAG D, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that ALUMAG D does not adversely affect their ability to do so (see section 4.8).

4.8 Undesirable effects

Tabulated list of adverse reactions

System organ class	**Frequency unknown** (cannot be estimated from the available data)
Immune system disorders	Hypersensitivity
Metabolism and nutrition disorders	Phosphate depletion**

Eye disorders	Blurred vision* Conjunctivitis
Cardiac disorders	Tachycardia* Palpitations* Arrhythmias*
Respiratory, thoracic and mediastinal disorders	Dry mouth* Thirst Bronchospasm Breathing problems (called “gasping syndrome”) in young children
Gastrointestinal disorders	Constipation * / ** Diarrhoea*** Nausea** Vomiting** Gastrointestinal discomfort
Skin and subcutaneous tissue disorders	Flushing and dryness of skin* Rash
Renal and urinary disorders	Urinary retention* Urine becomes alkaline

* Side effects that may occur because of dicyclomine.

** Side effects that may occur because of aluminium hydroxide.

*** Side effects that may occur because of magnesium oxide.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of ALUMAG D is important. It allows continued monitoring of the benefit/risk balance of ALUMAG D. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA online: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Toxic doses of dicyclomine cause tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion and excitement, and hallucinations passing into delirium. A rash may appear on the face and upper trunk. In severe intoxication, depression of the central nervous system may occur with hypertension or circulatory failure and respiratory depression.

Treatment includes pilocarpine to counteract the effect of dicyclomine. Further treatment is symptomatic.

Large doses of aluminium hydroxide may cause intestinal obstruction.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 11.4.2 Acid Neutralisers with antispasmodics.

Pharmacotherapeutic group: Antacids with antispasmodics.

ATC code: A02AG

Mechanism of action:

ALUMAG D has antacid properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol

Chloroform

Ethanol

Methyl hydroxyl ethyl cellulose

Nipastat

Oil cinnamon leaf

Peppermint oil

Purified water

Saccharin sodium

Silicone emulsion

Sodium cyclamate

Sodium lauryl sulphate

Sorbitol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Packed in 200 ml or 350 ml amber, round PVC bottles and 2,5 L amber, rectangular HDPE bottles.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pharmacorp (Pty) Ltd

29 Victoria Link

Route 21 Corporate Park

Irene, 0178

South Africa

8. REGISTRATION NUMBER: Z/11.4.2/0021

9. DATE OF FIRST AUTHORISATION: 13 May 2002

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