SCHEDULING STATUS

S2

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

Dicyclomine hydrochloride

Dried aluminium hydroxide

Light magnesium oxide

Contains sugar: Sorbitol 910 mg

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

Read all of this leaflet carefully because it contains important information for you

ALUMAG D is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ALUMAG D carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ALUMAG D with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What ALUMAG D is and what it is used for
2. What you need to know before you take ALUMAG D
3. How to take ALUMAG D
4. Possible side effects
5. How to store ALUMAG D
6. Contents of the pack and other information

1. What ALUMAG D is and what it is used for

ALUMAG D belongs to a group of medicines called acid neutralisers with antispasmodics.

ALUMAG D is indicated as an antacid.

2. What you need to know before you take ALUMAG D

Do not take ALUMAG D:

- if you are hypersensitive (allergic) to dicyclomine hydrochloride, dried aluminium hydroxide, light magnesium oxide or any of the other ingredients of ALUMAG D (listed in section 6)
- if you suffer from prostatic enlargement, intestinal obstruction or pyloric obstruction where it can lead to obstruction or severe inflammation of the colon
- if you suffer from a condition causing abnormal weakness of certain muscles, called myasthenia gravis
- if you suffer from glaucoma
- if you suffer from renal failure
- if you suffer from urinary tract disease, thyrotoxicosis (disease of thyroid gland) or heart failure.

Do not give ALUMAG D to children under two years.

Warnings and precautions

Take special care with ALUMAG D:

- if you suffer from conditions characterised by tachycardia (abnormal rapid heart rate)
- if ALUMAG D is given to elderly men
- if your stomach does not contract normally or if you have an obstruction in your stomach or intestines
- if you have a hernia associated with heartburn
- if you have kidney problems.

Other medicines and ALUMAG D

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Taking ALUMAG D with other medicines can decrease or increase the absorption of the other medicines. ALUMAG D should be taken at least 2 to 3 hours before or after other oral medicines.

Tell your doctor if you are taking any of the following:

- amantadine, used for Parkinson's disease
- antibiotics used to treat infection, called tetracyclines
- anticholinergic medicine, medicines that block the action of a neurotransmitter known as acetylcholine, thereby reducing spasms in smooth muscles
- antihistamines, used to treat allergies
- barbiturates, used for anxiety, sleeplessness, and epilepsy
- digoxin, a medication used to treat various heart conditions
- medicines used for certain mental conditions, such as butyrophenones, phenothiazines and tricyclic antidepressants
- quinidine, used to treat certain types of irregular heartbeats
- quinine, used to treat malaria
- vitamins
- warfarin, a medicine to help prevent blood clots.

Pregnancy and breastfeeding

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

ALUMAG D contains benzyl alcohol. Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ALUMAG D.

Driving and using 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 "**Possible side effects**").

ALUMAG D contains nipastat

ALUMAG D contains nipastat and may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm (a tight chest with difficulty breathing).

ALUMAG D contains benzyl alcohol

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.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

ALUMAG D contains sorbitol

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.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

ALUMAG D contains ethanol

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 sodium

ALUMAG D contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially ‘sodium-free’.

3. How to take ALUMAG D

Always take ALUMAG D exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are unsure.

The usual dose is:
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.

If you have the impression that the effect of ALUMAG D is too strong or too weak, talk to your doctor or pharmacist.

If you take more ALUMAG D than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ALUMAG D

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ALUMAG D can have side effects.

Not all side effects reported for ALUMAG D are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

Tell your doctor if you notice any of the following:

- hypersensitivity (allergy) which may appear as conjunctivitis or a skin rash
- flushing and dryness of the skin
- dry mouth, thirst
- bronchospasm (a tight chest with difficulty breathing)
- breathing problems (called “gasping syndrome”) in young children
- fatigue, sedation
- headache, dizziness
- blurred vision
- tachycardia (rapid heart rate) with palpitations and arrhythmias
- low phosphate levels in the body
- constipation, diarrhoea, nausea and vomiting, stomach discomfort
- urinary retention, urine becomes alkaline.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or other health care provider. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ALUMAG D.

In addition, side-effects can also be reported to info@pharmacorp.co.za.

5. How to store ALUMAG D

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ALUMAG D contains

The active substances in each 10 ml suspension are dicyclomine hydrochloride 5 mg, dried aluminium hydroxide 400 mg and light magnesium oxide 200 mg.

The inactive ingredients are 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.

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

What ALUMAG D looks like and contents of the pack

A white homogenous suspension with slight peppermint flavour.

Packed in 200 mL or 350 mL amber round PVC or PET bottles or 2,5 L amber, rectangular HDPE bottles

Not all pack sizes or containers may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

(and the translated Patient Information Leaflet)

www.pharmacorp .co.za