PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

1.NAME OF THE MEDICINE

ADCO MAYOGEL SUSPENSION

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains:

Aluminium hydroxide gel (dried)	600,00 mg
(equivalent to aluminium oxide)	282,00 mg
Magnesium trisilicate	600,00 mg
(equivalent to magnesium oxide)	120,00 mg
Alcohol	3,10 % *v/v*

Preservatives

Methylparaben	0,20 % *m/v*
Propylparaben	0,02 % *m/v*

Sugar free

Contains sweetener: saccharin sodium 9,00 mg

For a full list of excipients see section 6.1

3.PHARMACEUTICAL FORM

Suspension.

White suspension with odour of peppermint.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adco Mayogel Suspension is used for the relief of gastric acidity, dyspepsia and peptic ulcers.

4.2 Posology and method of administration

Posology

For use in adults only.

Two to three medicine measures one to three hours after meals and at bedtime, according to the need of the patient.

Do not exceed the maximum daily dosage of this product for more than two weeks, except under the advice and supervision of a doctor.

Method of administration:

Orally.

Shake the bottle before use.

4.3 Contraindications

Hypersensitivity to aluminium hydroxide, magnesium trisilicate or to any of the excipients (see section 6.1). In patients with impaired renal function.

4.4 Special warnings and precautions for use

- Do not take this product if you are presently taking a prescription antibiotic product containing any form of tetracycline.
- Do not use this product if you have kidney disease except under the advice and supervision of a doctor.
- Aluminium hydroxide may cause constipation. Aluminium hydroxide, like other aluminium compounds, is astringent and may cause constipation; large doses can cause intestinal obstruction.
- Excessive doses, or even normal doses in patients with low-phosphate diets, may lead to phosphate depletion accompanied by increased resorption and urinary excretion of calcium with the risk of osteomalacia.
- Osteomalacia, and also encephalopathy and dementia, can occur in patients with chronic renal failure who receive relatively high doses of aluminium hydroxide as a phosphate-binding agent.
- Impaired renal function may result in hypermagnesaemia. The symptoms of which include flushing of the skin, thirst, hypotension due to peripheral vasodilation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, cardiac arrhythmias, coma, and cardiac arrest.
- Aluminium hydroxide and magnesium trisilicate may interfere with the absorption of other drugs when these are taken concomitantly.

4.5 Interaction with other medicines and other forms of interaction

- Aluminium hydroxide and magnesium trisilicate may interfere with the absorption of other drugs when these are taken concomitantly.
- Aluminium-containing antacids may prevent the proper absorption of drugs such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin, H2 antagonists, atenolol, cyclines, diflunisal, digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazid, lincosamides, metoprolol, phenothiazine neuroleptics, penicillamine, propranolol and iron salts.

- **Polystyrene sulphonate**
  Concomitant use with polystyrene sulphonate has the potential risk of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure and of intestinal obstruction.

- **Quinidine**
  Concomitant use of aluminium products with quinidines may increase the serum levels of quinidine and lead to quinidine overdosage.

- **Tetracycline**
  Aluminium-containing antacids may prevent the proper absorption of tetracyclines. Adco Mayogel Suspension contains aluminium content and should not be used concomitantly with tetracycline-containing antibiotics or any tetracycline salts.

- **Citrates:**
  Concomitant use of aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

4.6 Fertility, pregnancy and lactation:

The safety of this medicine in pregnant women has not yet been established.

4.7 Effects on ability to drive and use machines:

The effect on the ability to drive and use machine has not been established.

4.8 Undesirable effects:

Frequency	System organ class	Undesirable effects
Less frequent	Gastrointestinal disorders	• Nausea • Vomiting • Constipation • Diarrhoea
Frequency Unknown	Gastrointestinal disorders	• Intestinal obstruction with large doses
	Metabolic and nutrition disorders	• Hypermagnesemia (Symptoms include: Cardiac arrest, Arrhythmias, Coma, Flushing of the skin, Loss of tendon reflexes, Muscle weakness, Respiratory depression) • Hyperaluminemia (May result in increased bone resorption hypercalciuria and Osteomalacia).

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorization 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**.**

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

4.9 Overdose:

Large doses may cause intestinal obstruction.

Excessive doses, or even normal doses in patients with low-phosphate diets, may lead to phosphate depletion accompanied by increased resorption and urinary excretion of calcium with the risk of osteomalacia. Osteomalacia, and also encephalopathy and dementia, can occur in patients with chronic renal failure who receive relatively high doses of aluminium hydroxide as a phosphate-binding agent.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

11.4.1 Antacids - Acid neutralisers

Mechanism of action

Antacid, with the capability to neutralise the acid in the stomach.

5.2 Pharmacokinetic properties

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients:

Aqua menthe piperitae concentrate,
Chloroform,
Natrosol 250,
Saccharin sodium,
Sodium lauryl sulphate,
Deionised water.

6.2. Incompatibilities:

Not applicable

6.3 Shelf life:

24 months

6.4 Special precautions for storage:

Store in a cool place at or below 25 °C in airtight containers.

6.5 Nature and contents of container:

100 ml, 200 ml, 350 ml, 375 ml, 500 ml, and 2,5 L bottles containing a white suspension with odour of peppermint. The bottle is placed in a carton.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685,
Customer Care: 0860 ADCOCK (232625)

8. REGISTRATION NUMBER

E/11.4.1/1732

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

14 March 1994

10. DATE OF REVISION OF THE TEXT

12 July 2023

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