

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S0**

ADCO MAYOGEL SUSPENSION, each 15 ml of suspension 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
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Sugar free

Contains sweetener:

Saccharin sodium	9,00 mg
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Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

ADCO MAYOGEL SUSPENSION is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ADCO MAYOGEL SUSPENSION carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Do not share ADCO MAYOGEL SUSPENSION with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

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1. WHAT ADCO MAYOGEL SUSPENSION IS AND WHAT IT IS USED FOR:

ADCO MAYOGEL SUSPENSION is an antacid, with the capability to neutralise the acid in the stomach.

ADCO MAYOGEL SUSPENSION is used for:

- The relief of stomach acidity, indigestion and peptic ulcers.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ADCO MAYOGEL SUSPENSION

Do not take ADCO MAYOGEL SUSPENSION:

- If you are hypersensitive (allergic) to aluminium hydroxide, magnesium trisilicate or to any of the other ingredients of ADCO MAYOGEL SUSPENSION (listed in section 6).
- If you have impaired renal (kidney) function.
- If you are pregnant. The safety of this medicine in pregnant women has not yet been established.

Warnings and precautions

- 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 and large doses may cause intestinal obstruction (blockage).
- 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 (softening of the bones).
- Osteomalacia (softening of the bones), and also encephalopathy (brain disease) and dementia (mental illness), can occur in patients with chronic renal failure who receive relatively high doses of Aluminium hydroxide as a phosphate-binding agent.
- Aluminium hydroxide and magnesium trisilicate may interfere with the absorption of other drugs when these are taken together.

Use in children and adolescents

For use in adults only.

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Other medicines and ADCO MAYOGEL SUSPENSION

- Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
- Aluminium hydroxide and magnesium trisilicate may interfere with the absorption of other drugs when taken concomitantly, so ADCO MAYOGEL SUSPENSION should not be taken at the same time as other medicines.

In particular, ADCO MAYOGEL SUSPENSION can affect the following medicines:

- Polystyrene sulphonate (used to treat increased amounts of potassium in the body)
- Medicines used to treat the heart such as quinidine, metoprolol, propranolol, digoxin and atenolol
- Iron salts (used to treat anaemia)
- H₂ Antagonist such ranitidine and cimetidine (used to treat stomach ulcer/ acidity)
- Chloroquine (used to treat Malaria)
- Bisphosphonates (used to treat bone disorders)
- Glucocorticoids (used to treat some allergic and abnormal allergic reactions)
- Ethambutol, rifampicin and isoniazid (used to treat tuberculosis)
- Fluroquinolones, lincosamides, ketoconazole, tetracycline and cephalosporins (used to treat infections)
- Phenothiazine neuroleptics (used to treat mental illness)
- Indomethacin and diflunisal (used to treat pain)
- Sodium fluoride (used in dental care)
- Levothyroxine (used to treat under reactive thyroid glands)
- Rosuvastatin (used to reduce cholesterol)
- Penicillamine (used to treat joint pains)
- Citrates
- Vitamins

ADCO MAYOGEL SUSPENSION with food and drinks

No available data.

Pregnancy, breastfeeding and fertility

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

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 health care provider for advice before taking this medicine.

Driving and using machines

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

It is not always possible to predict to what extent ADCO MAYOGEL SUSPENSION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ADCO MAYOGEL SUSPENSION affects them.

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3. How to take ADCO MAYOGEL SUSPENSION

Always take ADCO MAYOGEL SUSPENSION exactly as described in the leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor, pharmacists or nurse if you are not sure.

For use in adults only.

Two to three medicine measures one to three hours after meals and at bedtime.

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.

If you take more ADCO MAYOGEL SUSPENSION than you should:

- 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 (Softening of the bones).
- Osteomalacia, and also encephalopathy (Disease affecting the function and structure of the brain) and dementia (mental illness), can occur in patients with chronic renal failure (kidney failure), who receive relatively high doses of aluminium hydroxide as a phosphate-binding agent.
- Treatment is symptomatic and supportive.

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

4. Possible side effects

ADCO MAYOGEL SUSPENSION can have side effects.

Not all side effects reported for ADCO MAYOGEL SUSPENSION are included in this leaflet. Should your general health worsen or if you experience any unwanted effects while taking ADCO MAYOGEL SUSPENSION, please consult your health care provider for advice.

Less frequent side effects:

- Nausea
- Vomiting
- Constipation
- Diarrhoea

Frequency Unknown:

- Intestinal obstruction with large doses (A condition in which digested material is prevented from passing normally through the bowel).
- Hypermagnesemia (excess amount of magnesium in the blood). Hypermagnesemia may present with the following symptoms; heart attack, irregular heartbeat, coma, flushing of the skin, loss of tendon reflexes, muscle weakness, slow and ineffective breathing.
- Hyperalbuminemia (increased level of albumin in the blood), which may result in increased bone resorption hypercalciuria (too much calcium in the urine) and Osteomalacia (softening of the bones).

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

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Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ADCO MAYOGEL SUSPENSION. You may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. How to store ADCO MAYOGEL SUSPENSION.

Store in a cool place at or below 25 °C in airtight containers.
KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ADCO MAYOGEL SUSPENSION contains

Each 15ml 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

Excipients:

Aqua menthe piperitae concentrate, chloroform, natrosol 250, saccharin sodium, sodium lauryl sulphate, deionised water.

What ADCO MAYOGEL SUSPENSION looks like and contents of the pack:

100 ml, 200 ml, 350 ml, 375 ml, 500 ml, and 2,5 L bottles containing a white suspension with a peppermint odour.

The bottle is placed in a carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was revised in

12 July 2023

Registration Number

E/11.4.1/1732

BOTSWANA: B9323875 S4

NAMIBIA: NS0 04/11.4.1/1587

adcock ingram 

Date of Approval: 12 July 2023

31661 08/2023
31662 08/2023
31663 08/2023