Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product: GAVISCON DOUBLE ACTION LIQUID
Dosage: Suspension
Strength: Each 10 ml contains Sodium alginate 500 mg, sodium bicarbonate 213 mg and calcium carbonate 325 mg.
PIL Update: 21 December 2019
PIL Safety Update and New Indication: 15 February 2024

1.5.5.2.1 Annotated Proposed PIL for Gaviscon Double Action Liquid

SCHEDULING STATUS

S0

GAVISCON DOUBLE ACTION LIQUID

Sodium alginate 500 mg, sodium bicarbonate 213 mg, calcium carbonate 325 mg.

Preservatives: Methyl-hydroxybenzoate 0,4% m/v and Propyl-hydroxybenzoate 0,06% m/v

Sugar free

Contains sweetener: Sodium saccharin 0,1% m/v

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

GAVISCON DOUBLE ACTION LIQUID is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GAVISCON DOUBLE ACTION LIQUID carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GAVISCON DOUBLE ACTION LIQUID with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

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

1. What GAVISCON DOUBLE ACTION LIQUID is and what it is used for

GAVISCON DOUBLE ACTION LIQUID is a combination of two antacids (calcium carbonate and sodium

bicarbonate) and an alginate and works in two ways:

- Neutralising excess stomach acid to relieve the pain and discomfort.
- Forming a protective barrier over the stomach contents to soothe the burning pain in your chest.

GAVISCON DOUBLE ACTION LIQUID is used for gastric reflux (reflux of stomach contents into the oesophagus), reflux oesophagitis (inflamed food pipe), heartburn and indigestion.

2. What you need to know before you take GAVISCON DOUBLE ACTION LIQUID

Do not take GAVISCON DOUBLE ACTION LIQUID

• If you are hypersensitive (allergic) to sodium alginate, sodium bicarbonate, calcium carbonate or any of the other ingredients of GAVISCON DOUBLE ACTION LIQUID (listed in section 6).

• Contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

• If you have kidney disease, electrolyte imbalances (e.g. low calcium levels) or cirrhosis (complication of liver disease).

Warning and precautions

Take special care with GAVISCON DOUBLE ACTION LIQUID

• If you have heart disease or high blood pressure - GAVISCON DOUBLE ACTION LIQUID contains sodium (salt) and may worsen heart disease or high blood pressure.

Prolonged use of Gaviscon DOUBLE ACTION Liquid should be avoided.

Other medicines and GAVISCON DOUBLE ACTION LIQUID

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

Large doses of GAVISCON DOUBLE ACTION LIQUID may affect the absorption of other oral medicines.

A time interval of 2 hours should be considered between GAVISCON DOUBLE ACTION LIQUID intake and the administration of other medicines especially antihistamines, tetracyclines, digoxin, fluoroquinolones, iron salts, thyroid hormones, ketoconazole, neuroleptics (for mental illness), thyroxine, penicilamine, beta-blockers for heart conditions (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine (for malaria), bisphosphonates

(for osteoporosis), and estramustine (for prostate cancer).

GAVISCON DOUBLE ACTION LIQUID may increase blood levels of calcium if taken together with thiazide diuretics (water tablets) or vitamin D. Speak to your doctor if you are taking these medicines before you take GAVISCON DOUBLE ACTION LIQUID.

GAVISCON DOUBLE ACTION LIQUID with food and drink

This medicine is usually taken after meals and at bedtime.

Do not take GAVISCON DOUBLE ACTION LIQUID with large amounts of milk or milk-products. To do so may increase the risk of side effects.

Pregnancy, breast-feeding and fertility

Pregnancy and breast-feeding

No effects of GAVISCON DOUBLE ACTION LIQUID have been shown in breast fed newborns/infants of treated mothers. GAVISCON DOUBLE ACTION LIQUID can be used during breastfeeding.

If you are pregnant or breast-feeding 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.

Fertility

Clinical Data do not suggest that GAVISCON DOUBLE ACTION LIQUID has an effect on human fertility.

Driving and using machine

GAVISCON DOUBLE ACTION LIQUID has no or negligible influence on driving or the ability to operate tools or machines.

GAVISCON DOUBLE ACTION LIQUID contains calcium carbonate

High blood levels of calcium and acid rebound can occur following the regular use of high doses of calcium carbonate, especially in patients with a history of kidney problems.

3. HOW TO TAKE GAVISCON DOUBLE ACTION LIQUID

SHAKE WELL BEFORE USE.

Always take GAVISCON DOUBLE ACTION LIQUID exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults and children over 12 years: 10 - 20 ml after meals and at bedtime.

Children under 12 years: Not recommended except on medical advice.

Elderly: No dosage modifications necessary in this group

If you have the impression that the effect of GAVISCON DOUBLE ACTION LIQUID is too strong or too weak, tell your doctor or pharmacist.

Do not share medicines prescribed for you with any other person.

If you take more GAVISCON DOUBLE ACTION LIQUID than you should

Very large doses may cause bloating. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take GAVISCON DOUBLE ACTION LIQUID

If you miss a dose of this medicine and you are taking it regularly, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

GAVISCON DOUBLE ACTION LIQUID can have side effects.

Not all side effects reported for GAVISCON DOUBLE ACTION LIQUID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GAVISCON DOUBLE ACTION LIQUID, please consult your health care provider for advice.

If any of the following minor side effects continue, are severe or bother you, speak to your doctor or pharmacist:

- Stomach cramps, flatulence, constipation

If any of the following side effects occur, speak to your doctor immediately:

- Skin rash, hives, itching, problems with breathing.

Tell your doctor if you notice any of the following

Less frequent side effects

- Stomach cramps
- Flatulence
- Constipation
- Nausea
- Vomiting
- Diarrhoea
- Abdominal distension
- Abdominal cramps

Side effects with unknown frequencies

- Anaphylactic reaction
- Anaphylactoid reaction
- Hypersensitivity reactions such as urticaria
- Alkalosis
- Acid rebound
- Hypercalcaemia
- Milk-alkali Syndrome
- Respiratory effects such as bronchospasm

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 nurse. 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 GAVISCON DOUBLE ACTION LIQUID.

5. How to store GAVISCON DOUBLE ACTION LIQUID

Store at or below 25°C. Do not refrigerate.

Keep all medicines out of the reach and sight of children.

Do not store in bathrooms.

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

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What GAVISCON DOUBLE ACTION LIQUID contains

Each 10 ml contains: Sodium alginate 500 mg, sodium bicarbonate 213 mg and calcium carbonate 325 mg.

Preservatives: Methylhydroxybenzoate 0,4% m/v and Propylhydroxybenzoate 0,06% m/v.

Contains sweetener: Sodium saccharin 0,1% m/v

Other ingredients include: Carbomer, sodium hydroxide, peppermint flavour, and water.

What GAVISCON DOUBLE ACTION LIQUID looks like and contents of the pack

A viscous, opaque, off-white to cream suspension with an odour of peppermint.

GAVISCON DOUBLE ACTION LIQUID is available in amber glass bottles containing 150 ml, 300 ml, 600 ml or laminate foil sachets containing 10 ml suspension packed in 4, 12, 24 or 36 sachets per carton.

Holder of Certificate of Registration

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This leaflet was last revised in

16 August 2024

REGISTRATION NUMBER

A40/11.10/0480

Access to the corresponding Professional Information

Please go to the link for access to the corresponding PI: https://cpdcentre.co.za/product-inserts/Gaviscon-Double-Action-Liquid.pdf

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Contact details: 0861 11 1100

Namibia	11/11.10/0024 (NS0)
Malawi	Bottle: PMPB/PL485/2 (GSL); Sachet: PMPB/PL485/1 (GSL)
Botswana	BOT1302487 (A-J) (S4)
Zambia	Bottle: 133/024 (GS); Sachet: 133/029 (GS)
Zimbabwe	2017/16.1/5462 (HR)
Mauritius	Bottle: R12210/02/14; Sachets: R12215/02/14