SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM:

GAVISCON LIQUID ANISEED Suspension

COMPOSITION:

Each 10 ml of GAVISCON LIQUID ANISEED contains sodium alginate 500 mg and Sodium Bicarbonate 267 mg.

The other ingredients are calcium carbonate carbomer, sodium saccharin, fennel flavour, erythrosine, sodium hydroxide and water.

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

Contains sweetener (Saccharin sodium 0,100%m/v).

PHARMACOLOGICAL CLASSIFICATION:

A 11.10 Medicines acting on gastro-intestinal tract. Special combinations.

PHARMACOLOGICAL ACTION:

Pharmacodynamic Properties:

On ingestion sodium alginate and sodium bicarbonate reacts with saliva and gastric acid to produce a viscous gel, which floats on the stomach contents suppressing gastric reflux.

Pharmacokinetic properties:

In severe cases, the gel itself may be refluxed into the oesophagus where it helps protect the mucosa.

INDICATIONS:

GAVISCON LIQUID ANISEED is indicated for the following conditions: Gastric reflux, reflux oesophagitis, heartburn, including heartburn of pregnancy, and conditions associated with gastric reflux including hiatus hernia; flatulence; epigastric and retrosternal distress where the underlying cause is gastric reflux.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

Sodium bicarbonate should be administered with caution in patients with congestive heart failure , renal impairment and cirrhosis of the liver, hypertension and to patients receiving corticosteroids, patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

Hypocalcaemia/alkalosis can occur following the regular use of calcium carbonate.

Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Contains methyl parahydroxybenoate and propyl parahydroxybenzoate: May cause allergic reactions (possibly delayed)

INTERACTIONS:

Large doses of GAVISCON LIQUID ANISEED may affect the rate and/or the extent of absorption of other oral medicines.

A time-interval of 2 hours should be considered between GAVISCON LIQUID ANISEED intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, biphosphates and estramustine.

PREGNANCY AND LACTATION:

Pregnancy:

Clinical studies as well as post-marketing data indicate no malformative nor feto/neonatal toxicity of the active substances.

Lactation:

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

Fertility:

GAVISCON LIQUID ANISEED has no negative effect in parental or offspring fertility or reproduction.

Clinical data do not suggest that GAVISCON LIQUID ANISEED has an effect on human fertility.

Effects on ability to drive and use machines:

GAVISCON LIQUID ANISEED has no or negligible influence on driving or the ability to operate tools or machines

DOSAGE AND DIRECTIONS FOR USE:

For oral use.

SHAKE WELL BEFORE USE.

Adults and children over 12 years:	10 - 20 ml after meals and at bedtime.
Children under 12 years:	Should be given only on medical advice.

Renal insufficiency: Caution if highly restricted salt diet is necessary (see “WARNINGS”)

Duration of treatment: If symptoms do not improve after seven days, the clinical situation should be reviewed by a medical practitioner.

SIDE-EFFECTS

Adverse reactions have been ranked under headings of frequency using the following convention: Very common: ≥ 1/10; Common: ≥ 1/100 to < 1/10; uncommon: ≥ 1/1,000 to <1/100; rare: ≥ 1/10,000 to <1/1,000; very rare: <1/10,000; Not known: cannot be estimated from the available data.

Immune system disorders:

Not known: Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.

Respiratory, thoracic and mediastinal disorders:

Not known: respiratory effects such as bronchospasm

Gastroinestinal disorders: Administration of sodium bicarbonate can cause stomach cramps and flatulence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Very large doses may produce a feeling of abdominal distension. Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:

An opaque pink suspension with an odour of fennel.

PRESENTATION:*

Amber glass bottles containing 150 ml, 200 ml, 250 ml, 300 ml, 500 ml or 600 ml.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a dry place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

L/11.10/1

NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION:

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11. DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION:

Date on the registration certificate: 20 April 1979

Date of the most recently revised professional information leaflet: 17 January 2020

Zimbabwe	2013/16.1/4820 (HR)
Mauritius	R12208/02/14
Zambia	133/005 (GS)
Namibia	19/32.2/0017 (NS0)

Approval Date	**Version Number**	**Description**
20/04/1979	V0	Product Registration
18/12/2019	V1	Safety Update
17/01/2020	V2	Safety Update