GAVISCON ADVANCE PEPPERMINT

Each 5 ml suspension contains sodium alginate 500 mg

Package Insert Amendment

SCHEDULING STATUS **S0**

PROPRIETARY NAME (AND DOSAGE FORM)

Gaviscon® Advance Peppermint (Suspension)

COMPOSITION

Each 5 ml contains Sodium Alginate 500 mg in a thickened base

Preservatives:

Methylhydroxybenzoate	0.4% m/v
Propylhydroxybenzoate	0.06% m/v

PHARMACOLOGICAL CLASSIFICATION

A11.10 Medicines acting on gastro-intestinal tract. Special combinations.

PHARMACOLOGICAL ACTION

On ingestion sodium alginate reacts with saliva and gastric acid to produce a viscous gel which floats on the stomach contents suppressing gastric reflux. In severe cases, the gel itself may be refluxed into the oesophagus where it helps protect the mucosa.

Pharmacodynamics:

The mechanism of action of this product is physical and does not depend on absorption into the systemic circulation.

On ingestion the product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near-neutral pH.

This raft floats on top of the stomach contents, quickly and effectively impeding gastro- oesophageal reflux for up to 4 hours. In severe cases the raft itself may be refluxed into the oesophagus in lieu of the stomach contents and exert a demulcent effect.

Pharmacokinetics:

Alginate is an indigestible polysaccharide which acts as a source of dietary fibre, eventually breaking down and passing naturally through the digestive system.

INDICATIONS

Gaviscon® Advance Peppermint is indicated for the following conditions: Gastric reflux, reflux oesophagitis, heartburn, including heartburn of pregnancy, hiatus hernia, and flatulence associated with gastric reflux and all cases of epigastric and retro-sternal distress, where the underlying cause is gastric reflux.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients

WARNINGS AND SPECIAL PRECAUTIONS

Consult a doctor if symptoms persist or worsen after 7 days.

Uncommon:

Gastro intestinal disorders: Stomach cramps, flatulence

Very rare (<1/10 000)

Hypersensitivity: Urticaria, bronchospasm

Respiratory disorders: Bronchospasm

Musculo-skeletal disorders: Abdominal distention and abdominal cramps

Gastro-intestinal disorders: Nausea, vomiting and diarrhoea

Sodium: Each 5ml dose of **Gaviscon® Advance peppermint** contains 53 mg (2.3 mmol) of sodium.

To be taken into consideration by patients on a controlled sodium diet (e.g. in some cases of congestive heart failure and renal impairment).

Nausea, vomiting, diarrhea and abdominal cramps may occur.

Potassium: Each 5 ml of Gaviscon Advance Aniseed contains 39 mg (1.0 mmol) of potassium.

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

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None known.

INTERACTIONS

None known.

PREGNANCY AND LACTATION

This medicine can be used as directed during pregnancy and lactation.

Pregnancy:

Clinical studies in more than 500 pregnant women as well as a large amount of data from post-marketing

experience indicate no malformative nor feto/ neonatal toxicity of the active substances.

Gaviscon can be used during pregnancy, if clinically needed.

Lactation/breastfeeding:

No known effect on breastfed infants.

Gaviscon can be used during breast-feeding.

Fertility:

No known effect on human fertility.

DOSAGE AND DIRECTIONS FOR USE

For oral use.

SHAKE WELL BEFORE USE

Adults and children over 12 years: 5 – 10 ml after meals and at bedtime

Children under 12 years: Should be given only on medical advice.

Special patient groups:

Elderly: No dose modifications are required in this age group.

Hepatic Impairment: No modifications necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary

Duration of treatment:

Consult a doctor if symptoms persist or worsen after 7 days.

SIDE EFFECTS:

Immune system disorders: Not known

Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as bronchospasm and urticaria.

Reporting suspected adverse reactions after authorisation of the medicinal product is important.

It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Very large doses may produce a feeling of abdominal distention. Treatment of overdosage is symptomatic and suppo

IDENTIFICATION

An off – white suspension with an odour and flavour of peppermint.

PRESENTATION

Amber glass bottles containing 150 ml, 180 ml, 200 ml, 500 ml or 600 ml.

Aluminium foil sachets containing 5 ml or 10 ml per sachet. Each cardboard container contains 10 sachets.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a well closed container. Do not refrigerate

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER

A40/11.10/0049

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

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

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