SCHEDULING STATUS: [S0]

PROPRIETARY NAME (AND DOSAGE FORM):
GAVISCON LIQUID PEPPERMINT (Suspension)

COMPOSITION:
Each 10 ml of Gaviscon Liquid Peppermint contains sodium alginate 500 mg in a thickened base containing sodium bicarbonate, calcium carbonate and saccharin.
Preservatives:
Methylhydroxybenzoate 0, 4% m/v
Propylhydroxybenzoate 0, 06% m/v

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

PHARMACOLOGICAL ACTION:
On ingestion GAVISCON LIQUID PEPPERMINT 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.

INDICATIONS:
GAVISCON LIQUID PEPPERMINT is indicated for the following conditions: Gastric reflux, reflux oesophagitis, heartburn, including heartburn of pregnancy, hiatus hernia, 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:
Each 10 ml dose GAVISCON LIQUID PEPPERMINT contains 145 mg (6,3 mmol) of sodium. As congestive cardiac failure may result from excessive sodium absorption, GAVISCON LIQUID PEPPERMINT should be administered with caution to patients on a highly restricted salt diet.

INTERACTIONS:

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

PREGNANCY AND LACTATION:

Problems with taking GAVISCON LIQUID PEPPERMINT during lactation have not been documented.

DOSAGE AND DIRECTIONS FOR USE:

SHAKE WELL BEFORE USE.

Adults and children over 12 years:	10 - 20 ml after meals and at bedtime.
Children under 12 years:	10 ml after meals and at bedtime.
Children under 2 years:	Although GAVISCON LIQUID PEPPERMINT are not normally recommended for children under the age of two, where the physician considers its use necessary, a dose of 5 ml should not be exceeded.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Uncommon:

- Gastrointestinal disorders: Stomach cramps, flatulence

Very rare (<1/10 000)

- Hypersensitivity: Urticaria, bronchospasm

Special precautions:

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

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

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:

Opaque, off-white to cream suspension with a flavour of peppermint.

PRESENTATION:*

Amber glass bottles containing 150 ml, 300 ml or 600 ml.

STORAGE INSTRUCTIONS:

Store below 25 °C. Do not refrigerate.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

29/11.10/0641

NAME AND BUSINESS ADDRESS OF APPLICANT:

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*On the printed version, pack sizes may be limited to those actually marketed.