

## Prescribing information for Gaviscon Double Action Mint PL 00063/0552

**ACTIVE INGREDIENTS:** 10ml dose: sodium alginate 500mg, sodium bicarbonate 213mg, calcium carbonate 325mg.

**INDICATIONS:** Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, e.g. following meals or during pregnancy, and for symptoms of hyperacidity. Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

**DOSAGE INSTRUCTIONS:** For oral use. Adults and children 12yrs and over: 10-20ml after meals and at bedtime, up to 4 times/day. Children under 12yrs.: Only on medical advice. Elderly: No dose modifications necessary.

**CONTRAINDICATIONS:** Hypersensitivity to any ingredients, including the esters of hydroxybenzoates (parabens).

**PRECAUTIONS AND WARNINGS:** Each 20 ml dose has a sodium content of 254.5 mg (11.06 mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment. Each 20 ml contains 260 mg (6.5 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. If symptoms do not improve after 7 days, the clinical situation should be reviewed.

Due to the presence of calcium carbonate (antacid) an interval of 2 hrs should be considered between Gaviscon intake and the administration of other medicinal products, especially H<sub>2</sub>-antihistaminics tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, and diphosphonates.

**PREGNANCY AND LACTATION:** Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of Gaviscon on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience the medicinal product may be used during pregnancy and lactation.

**SIDE-EFFECTS:** Very rarely (<1/10,000) patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. Ingestion of large quantities of calcium carbonate may cause alkalosis, hypercalcaemia, acid rebound, milk alkali syndrome or constipation. These usually occur following larger than recommended dosages.

**NHS PRICE:** 500 ml £2.56 (ex VAT).

**Supply Classification:** GSL.

**MAH:** RB UK Commercial Limited, Dansom Lane, Hull, HU8 7DS.

**Date of Preparation:** May 2016.

**All adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Reckitt Benckiser Healthcare UK Ltd on 0333 2005 345.**