## References


1. Heading RC, *et al. Eur J Gastroenterol Hepatol*. 2016;28:455–462.
2. Heartburn and acid reflux. NHS UK. Available at: https://www.nhs.uk/conditions/heartburn-and-acid-reflux/. Accessed June 2023.
3. Watanabe M, *et al. BMC Gastroenterol*. 2017;17:92.
4. Broderick R, *et al. Dig Dis*. 2020;38.188–195.
5. Indigestion. NHS UK. Available at: https://www.nhs.uk/conditions/indigestion/. Accessed June 2023.
6. Gaviscon Double Action Mint Oral Suspension. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/5609/smpc. Accessed June 2023.



## Essential Information

Gaviscon Double Action Mint Oral Suspension **Active Substances:** Each 10 ml dose contains sodium alginate 500 mg, sodium bicarbonate 213mg and calcium carbonate 325 mg. **Indications:** Treatment of symptoms resulting fromthe reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity). Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy. **Posology and method of Administration:** For oral administration. ●Adults and children 12 years and over: 10-20 ml after meals and at bedtime, up to four times per day. ●Children under 12 years: Should be given only on medical advice. ●Elderly: No dose modifications necessary for this age group. ●Hepatic Impairment: No dose modification necessary. ●Renal Insufficiency: Caution if highly restricted salt diet is necessary. **Contraindications:** Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients. **Special warnings and precautions for use:** This medicinal product contains 255.76 mg (11.12 mmol) sodium per 20 ml dose, equivalent to 12.79 % of the WHO recommended maximum daily intake for sodium. ●The maximum daily dose of this product is equivalent to 51.15% of the WHO recommended maximum daily intake for sodium. ●This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment). ●Each 20 ml contains 260 mg (6.5mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. ●Treatment of children younger than 12 years of age is not generally recommended, except on medical advice. If symptoms persist, or treatment is required for more than 7 days continuously, medical advice should be sought. As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical condition s. ●Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed). This medicine contains 2.1 mg benzyl alcohol (from Fennel flavour) per 20 ml dose. Benzyl alcohol may cause allergic reactions. **Fertility, pregnancy and lactation:** ● Pregnancy: 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 usedduring pregnancy, if clinically needed. ●Breastfeeding: No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. This product can be used during breast-feeding if clinically needed. ●Fertility: Clinical data do not suggest that this product has an effect on human fertility. **Side effect:** Adverse events which have been associated with sodium alginate, sodium bicarbonate and calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

| SYSTEM ORGAN CLASS | FREQUENCY | ADVERSE EVENTS |
|---|---|---|
| Immune System Disorders | Very Rarely | Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity reactions such as urticaria. |
| Metabolism and Nutritional Disorders | Not Known | Alkalosis1, acid rebound1, Hypercalcaemia1, Milk-alkali Syndrome1 |
| Respiratory, Thoracic and Mediastinal Disorders | Very Rarely | Respiratory effects such as bronchospasm. |
| Gastrointestinal Disorders | Not Known | Constipation1 |

**Legal Classification:** GSL. **Licence Holder:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom. **Licence Number:** PL 00063/0552. **MRRP:** £5.49 for 150 ml, £8.99 for 300 ml, £10.79 for 500 ml & £15.09 for 600 ml. **Last Revised:** February 2021.

**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0333 200 5345**

Gaviscon Double Action Mint Flavour Chewable Tablets **Active Substances:** Each tablet contains sodium alginate 250 mg, sodium bicarbonate 106.5 mg and calcium carbonate 187.5 mg. **Indications:** Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity). Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy. **Posology and method of Administration:** For oral administration. ●Adults and children 12 years and over: 10-20 ml after meals and at bedtime, up to four times per day. ●Children under 12 years: Should be given only on medical advice. ●Elderly: No dose modifications necessary for this age group. ●Hepatic Impairment: No dose modification necessary. ●Renal Insufficiency: Caution if highly restricted salt diet is necessary. **Contraindications:** Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients. **Special warnings and precautions for use:** This medicinal product contains 223.56 mg (9.72 mmol) sodium per 4 tablet dose, equivalent to 11.18 % of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 44.71% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment). Each 4 tablet dose contains 300 mg (7.5 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. Treatment of children younger than 12 years of age is not generally recommended, except on medical advice. If symptoms persist, or treatment is required for more than 7 days continuously, medical advice should be sought. As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions. This medicinal product contains aspartame (E951), a source of phenylalanine. May be harmful for people with phenylketonuria. This medicine contains Carmoisine lake (E122). This may cause allergic reactions. Fertility**, pregnancy and lactation:** ● Pregnancy: 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 usedduring pregnancy, if clinically needed. ●Breastfeeding: No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. This product can be used during breast-feeding if clinically needed.
●Fertility: Clinical data do not suggest that this product has an effect on human fertility. **Side effect:** Adverse events which have been associated with sodium alginate, sodium bicarbonate and calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

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|---|---|---|
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| Metabolism and Nutritional Disorders | Not Known | Alkalosis1, acid rebound1, Hypercalcaemia1, Milk-alkali Syndrome1 |
| Respiratory, Thoracic and Mediastinal Disorders | Very Rarely | Respiratory effects such as bronchospasm. |
| Gastrointestinal Disorders | Not Known | Constipation[1] |

**Legal Classification:** GSL. **Licence Holder:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom. **Licence Number:** PL 00063/0525. **MRRP:** £3.79 for 12s, £5.99 for 24s & £9.79 for 48s. **Last Revised:** August 2019.

**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0333 200 5345**