

Pharmacode Reads This Way  
Last Bar  
First Bar

PRO  
FPI

**GAVISCON INFANT**  
Powder for Oral Suspension,  
Sodium alginate 225mg and Magnesium alginate 87.5mg  
**PATIENT INFORMATION LEAFLET**

**Please read all of this leaflet carefully because it contains important information for you and your child.**

This medicine is available without prescription. However, you still need to use Gaviscon Infant carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your child's symptoms worsen or do not improve after 7 days.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Gaviscon Infant is and what it is used for
2. Before using Gaviscon Infant
3. How to use Gaviscon Infant
4. Possible side effects
5. How to store Gaviscon Infant
6. Further Information

**1. What Gaviscon Infant is and what it is used for?**

Gaviscon Infant contains sodium alginate and magnesium alginate which belong to a group of medicines called "reflux suppressants".

Reflux is the process by which the stomach contents flow back up the tube that leads from the mouth to the stomach (known as the gullet or oesophagus). This can cause an infant to be sick, spit up more than normal and become distressed. Gaviscon Infant prevents reflux by stabilising the stomach contents, so reducing the incidence of reflux and bringing up of feeds (possetting).

**2. Before using Gaviscon Infant:**

**Do not use Gaviscon Infant:**

- except on a doctor's or other healthcare professional's recommendation
- if your child is allergic to magnesium alginate, sodium alginate or any of the other ingredients (see section 6)
- if your child is being sick, has a fever or diarrhoea
- if you have been told or it is suspected that your child has damage to their kidneys or they have been put on a low salt diet
- if you have been told that your child has a blockage in their gut (an intestinal obstruction)

**Take special care with Gaviscon Infant:**

If your baby is premature or under one year, you should ask your doctor or pharmacist before giving Gaviscon Infant. There have been extremely rare reports of altered stool consistency (e.g., constipation and diarrhoea) in relation to use of this product. If you are concerned or you notice significant or sustained changes in bowel habit, consult a healthcare professional immediately.

**Taking Gaviscon Infant with other medicines**

Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription.

**Taking Gaviscon Infant with food and drink**

**Do not** use Gaviscon Infant with other feed thickening agents or infant milk preparations containing a thickening agent. You should ask your doctor or pharmacist before you give Gaviscon Infant to your child if you are not sure.

**Important information about some of the ingredients of Gaviscon Infant**

This medicinal product contains 0.9 mmol (or 21 mg) sodium per sachet. To be taken into account by patients on a controlled sodium diet.

**3. How to use Gaviscon Infant**

Always use Gaviscon Infant exactly as described below. You should check with your doctor or pharmacist if you are not sure. Gaviscon Infant should **not** be used in premature infants or those under one year of age except under medical supervision.

The dosage and mixing instruction depend on the age and weight of your child and the feeding method you use:

Open the sachet and mix the contents immediately before use as directed below:

**Breast fed infants aged 1-2 years:** Under 4.5 kg (10 lb) – one sachet  
Over 4.5 kg (10 lb) – two sachets

- Put the powder in a glass and add 5 ml (one teaspoon) of cooled, boiled water
- Mix to a smooth paste
- Add another 10 ml (two teaspoons) of the water and mix again
- Give to your infant after each feed using a spoon or feeding bottle

RB94267

**Bottle fed infant aged 1-2 years: Under 4.5 kg (10 lb) – one sachet**

- Mix into not less than 115 ml (4 fluid oz) of each feed in the bottle
- Shake well

**Over 4.5 kg (10 lb) – two sachets**

- Mix into not less than 225 ml (8 fluid oz) of each feed in the bottle
- Shake well

**Do not** give more than six times in 24 hours.

**If your child's condition persists or becomes worse ask your doctor or other healthcare professional for advice immediately.**

You **should not** use Gaviscon Infant for more than seven days without checking with your doctor or other healthcare professional.

**If your child takes more Gaviscon Infant than they should**

If your child takes too much Gaviscon Infant they may be sick, lose their appetite, become irritable or tired and weak.

If you accidentally give too much Gaviscon Infant ask your doctor or other healthcare professional for advice **immediately**.

**If you forget to give Gaviscon Infant**

If a dose is missed **do not** give a double dose with the next feed. Just carry on with the recommended dose.

If you have any further questions on the use of this product ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Gaviscon Infant can cause side effects, although not everybody gets them.

Very rarely, Gaviscon Infant can cause bloating and discomfort of the stomach (gastric distension).

Very rarely, there have been reports of altered stool consistency, including symptoms of constipation and diarrhoea.

If the child has any side effects after taking Gaviscon Infant tell your doctor or other healthcare professional.

**Reporting of side effects**

Ireland: If you get any side effects, talk to your doctor, pharmacist or nurse. You can report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

**5. How to store Gaviscon Infant**

**Keep all medicines out of reach and sight of children.**

Do not use after the expiry date shown on the pack (EXP month/year).

Do not store above 30°C.

Do not use if the sachet is damaged or the security seal is broken.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Further information**

Each dose of Gaviscon Infant powder contains 225 mg sodium alginate and 87.5 mg magnesium alginate as the active ingredients.

The other ingredients are mannitol (E421) and colloidal silica.

**What Gaviscon Infant looks like and the contents of the pack**

Gaviscon Infant is a powder for oral suspension.

Each carton contains 30 sachets joined in pairs.

**Marketing Authorisation Holder and Manufacturer**

The Manufacturer is Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, UK.

Product Authorisation Holder in Ireland is Reckitt Benckiser Ireland Limited, 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Product Authorisation Holder in Australia is Reckitt Benckiser, 44 Wharf Rd., West Ryde, NSW 2114, Australia.

Product Authorisation Holder in New Zealand is Level 1, 2 Fred Thomas Drive, Takapuna, Auckland, New Zealand.

Leaflet last revised February 2015.

RB94267

**CUSTOMER INFO:**  
Minimum Point Size = 9.00pt

**RB Artwork and Print Specification**

Trident Reference No: RB194267  
 ZEN Ref: TR996417  
 Action: **B**  
 Brand: Gaviscon  
 Category: Infant  
 Segment Group: Powder  
 Segment: Sachet  
 Pack Size: NaSachets  
 Market/Country: EIRE  
 Date: 24/08/15

RBH Contact: Jennifer Shannon

**Artwork Type: IDM Submission**

Component Code (2D if applicable): RB94267  
 Parent Technical Packaging  
 Specification: D0303972  
 Finished Goods Code: Na  
 Supply Point: RB Hull  
 Pharmacode No/NE: N/A  
 Edgemark Position: Na

CAD Cam Ref: Q-Lft-D0303972-256x130mm  
 Printer: Essentra Packaging (Bradford, UK)  
 Substrate: Paper White

Technical & Non Printing Items  
 Cutter 2 (if applicable)  
 Guides 2 (if applicable)

Colours (Leaflet)  
 Process Black  
 TH

**BARCODE INFO**

Barcode Type: N/A  
 Barcode Number: N/A  
 Magnification: N/A  
 Truncated By: N/A  
 Full Height: N/A  
 Bar Height (smallest Bar): N/A  
 BWR: N/A  
 Encoded Data: N/A



Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

STUDIO USE ONLY Samantha Keyworth v2.0  
 Sm\*Art check results: G=1;O=0;R=0; -SK-24/08/15 12:47:51

**ARTWORK APPROVAL**

Approved by Sonoco Trident on behalf of Reckitt Benckiser

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

NOT APPROVED FOR COLOUR

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

290  
280  
270  
260  
250  
240  
230  
220  
210  
200  
190  
180  
170  
160  
150  
140  
130  
120  
110  
100  
90  
80  
70  
60  
50  
40  
30  
20  
10  
mm

RB94267