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?
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 (posseting).

2. Before using Gaviscon Infant
Do not use Gavsicon 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 Gavsicon 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: 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

Bottle fed infant: **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

Young children: Two sachets, prepared as for breast fed infants (above), to be taken after each meal.
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
In Ireland: If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland, Tel: +35316764971, Fax: +35316762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

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 Reckitt Benckiser,
289 Lincoln Rd., Henderson, Auckland 1231, New Zealand.
Leaflet last revised November 2013.

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Production line			
Manufacturing site			
Pack Tech approver	1st	2nd	
Date			
Check Criteria	**Details & Comments**	**Checks**	
Approvals		1st	2nd
Market Approval			
Regulatory Approval			
3rd Party Approval			
Technical Drawing/Cutter ref no.			
PPI component code correct on artwork?			
Correct drawing for the production line?			
Profile shape & dimensions			
Graphics layout/orientation			
Unwind diagram (PPTD1022/1-20)			
Printable areas/bleed			
Varnish free areas			
Variable coding position & dimensions			
Varnish and print requirements			
Pre-printed headers (alignment and suitability)			
Embossing, Braille & Foil Blocking			
Separations on artwork			
Alignment within cutter			
Braille structure			
Verification Code Type; Pharma Code / 2D / OCV			
Bar sequence and/or number correct Position			
Size (height, width, spacing, font)			
Direction of read			
Light margins and print free areas			
Colour			
Repeat distance (reeled material)			
Bar code Type; EAN, ITF, Code39, etc			
Magnification / width and height			
Colour (e.g. black print on white background)			
Light margins & indicators			
Bearer bars & H gauges (if required)			
Symbol grade (Pass = A,B,C; Action = D,F)			
Bar code number (human readable)			
Bar code number (encoded & hidden data)			
Confirm bar code number from source			
Cross check related docs (JDE/PID)			
Photo-electric cell mark / edge marks			
Present & per Tech drawing?			
Correct pitch?			
Additional markings			
e-mark, recycle logo etc			
Legend box (RB specification)			
Correct component code			
Correct D spec			
Correct printer			
Correct Substrate			
A/W is set up appropriately for this substrate			
Edge mark details			
Pharmacode details			
Colours & print process			
Varnish			
Barcode information			
General details are correct			
Pass / Fail comments and Signature			

By approving the artwork referenced within this form I authorise it for release to the print supplier

Additional Comments

Version 001 14/2/2011

RB Artwork and Print Specification

Trident Reference No: RB140821
ZEN Ref: TR759370
Action: A
Brand: Gaviscon
Category: Infant
Segment Group: Powder
Segment: Sachet
Pack Size: NAunit
Market/Country: EIRE
Date: 17/02/14

RBH Contact: Jennifer Shannon

Artwork Type: Commercial

Component Code (2D if applicable): 3002610
Parent Technical Packaging Specification: D0303972
Finished Goods Code: Na
Supply Point: RB Hull
Pharmacode No/NE: 10110(53)
Edgemark Position: Na

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

Technical & Non Printing Items

- Cutter
- Cutter 2 (if applicable)
- Guides
- Guides 2 (if applicable)

Colours

Process Black 1 LTH

BARCODE INFO

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

Reckitt Benckiser

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ARTWORK APPROVAL

Approved by Sonoco Trident on behalf of Reckitt Benckiser

Signed: _

Date: _

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