

## Package Leaflet: Information for the user

Gaviscon Infant  
Powder for Oral Solution  
Sodium alginate 225mg and Magnesium alginate 87.5mg

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you and your child.**

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advise.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).
- You must contact a doctor if your child's symptoms worsen or do not improve after 7 days.

### What is in this leaflet:

1. What Gaviscon Infant is and what it is used for?
2. What you need to know before using Gaviscon Infant
3. How to use Gaviscon Infant
4. Possible side-effects
5. How to store Gaviscon Infant
6. Contents of the pack and other 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 feeds (possetting).

### 2. What you need to know before using Gaviscon Infant

#### Do not use Gaviscon Infant:

- Except on 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)

#### Warnings and precautions

##### 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 medicine contains 23.9mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 1% of the recommended maximum daily dietary intake of sodium for an adult.

### 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 directly below:

#### Breast fed infants aged 1-2 years:

Under 4.5kg (10lb) – one sachet

Over 4.5kg (10lb) – two sachets

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

#### Bottle fed infants aged 1-2 years:

Under 4.5kg (10lb) – one sachet

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

Over 4.5kg (10lb) – two sachets

- Mix into not less than 225ml (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 you 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 a rash and bloating & discomfort of the stomach (gastric distension).

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

If your child gets any side effects after taking Gaviscon Infant talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

### 5. How to store Gaviscon Infant

Keep this medicine out of the sight and reach 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. Contents of the pack and other information

Each dose of Gaviscon Infant powder contains 225mg sodium alginate and 87.5mg 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

Manufacturers: Reckitt Benckiser Healthcare (UK) Ltd., Hull, HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

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, Sydney, Australia.

Product Authorisation Holder in New Zealand is Reckitt Benckiser (New Zealand) Ltd., Level 1, 2 Fred Thomas Drive, Takapuna, Auckland, New Zealand.

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