PACKAGE LEAFLET: INFORMATION FOR THE USER
Gaviscon Infant Powder for Oral Suspension
Sodium alginate 225 mg and Magnesium alginate 87.5 mg

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child has any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 the active substances 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) in infants and young children aged 1 to 24 months.

2. WHAT YOU NEED TO KNOW 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 any of the ingredients of Gaviscon Infant (listed in 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
Talk to your doctor or pharmacist before using Gaviscon Infant if your baby is premature or under one month.

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.

If your child's symptoms persist after 7 days consult your doctor.

Other medicines and Gaviscon Infant
Tell your doctor or pharmacist if your child is taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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.

Gaviscon Infant contains sodium
This medicine contains 23.9 mg 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 TAKE THIS MEDICINE

Always use Gaviscon Infant exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For infants aged 1 to 24 months. Gaviscon Infant should **not** be used in premature infants or those under 1 month of age unless advised by your doctor.
Not suitable for children over 24 months (2 years), adults or the elderly.
For infant 1-12 months: Please seek medical advice before taking the product.

The dosage and mixing instructions depend on the weight of your child and the feeding method you use:
Infants under 4.5 kg (10 lb) – one sachet should be used
Infants over 4.5 kg (10 lb) – two sachets should be used

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

Bottle fed infants:	• Mix each sachet into 115 ml (4 fluid oz) of milk feed in the bottle • Shake well • Feed as normal
Breast fed infants and other infants 1 month to 24 months (2 years) of age:	• Mix each sachet with 5 ml (1 teaspoon) of cooled, boiled water until a smooth paste is formed • Add another 10 ml (2 teaspoons) of cooled, boiled water and mix • For breast fed infants give Gaviscon Infant part way through each feed or meal using a spoon or feeding bottle • For all other infants give Gaviscon Infant at the end of each meal using a spoon or feeding bottle

Do not give more than six times (maximum of 6 or 12 sachets depending on the weight of your child) 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 suffer from intestinal obstructions, be sick, lose their appetite, become irritable or tired and weak.

If you accidently 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** 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 (less than 1 in 10,000 patients) patients may experience constipation and diarrhoea. Side effects for which the frequency cannot be estimated from available data include a rash, bloating, discomfort of the stomach (gastric distention) and intestinal obstruction.

If the child has any side effects, stop giving Gaviscon Infant and tell your doctor or other healthcare professional.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE THIS MEDICINE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Gaviscon Infant contains:

The active substances in each Gaviscon Infant sachet are 225 mg sodium alginate and 87.5 mg magnesium alginate. 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 of powder joined in pairs.

Manufacturer and Product License Holder in UK:
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