

Sodium Alginate Magnesium Alginate

GAVISCON Infant

225mg/87.5mg Powder for Oral Suspension
Antacid/ Anti-Reflux

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 5.

1. NAME, DESCRIPTION AND STRENGTH OF THE MEDICINE.

WHAT IS IN THE MEDICINE?

The active substances in each Sodium Alginate/Magnesium Alginate (Gaviscon Infant) sachet are 225 mg sodium alginate and 87.5 mg magnesium alginate. The other ingredients are mannitol (E421) and colloidal silica.

Sodium Alginate/Magnesium Alginate (Gaviscon Infant) is a powder for oral suspension.

2. WHAT SODIUM ALGINATE/MAGNESIUM ALGINATE (GAVISCON INFANT) IS AND WHAT IT IS USED FOR?

Sodium Alginate/Magnesium Alginate (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. Sodium Alginate/Magnesium Alginate (Gaviscon Infant) prevents reflux by stabilising the stomach contents, so reducing the incidence of reflux and bringing up of feeds (possetting) in infants and young children aged 1 to 24 months.

3. HOW MUCH AND HOW OFTEN SHOULD YOU USE SODIUM ALGINATE/MAGNESIUM ALGINATE (GAVISCON INFANT)?

Always use Sodium Alginate/Magnesium Alginate (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. Sodium Alginate/Magnesium Alginate (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.

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	<ul style="list-style-type: none"> • 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 up to 24 months (2 years) of age	<ul style="list-style-type: none"> • 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 Sodium Alginate/Magnesium Alginate (Gaviscon Infant) part way through each feed or meal using a spoon or feeding bottle • For all other infants give Sodium Alginate/Magnesium Alginate (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 Sodium Alginate/Magnesium Alginate (Gaviscon Infant) for more than seven days without checking with your doctor or other healthcare professional.

4. WHEN SHOULD YOU NOT TAKE SODIUM ALGINATE/MAGNESIUM ALGINATE (GAVISCON INFANT)? CARE THAT SHOULD BE TAKEN WHEN TAKING SODIUM ALGINATE/MAGNESIUM ALGINATE (GAVISCON INFANT)?

Do not use Sodium Alginate/Magnesium Alginate (Gaviscon Infant):

- Except on a doctor's or other healthcare professional's recommendation
- If your child is allergic to any of the ingredients of Sodium Alginate/Magnesium Alginate (Gaviscon Infant) (listed in section 1)
- 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)

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Warnings and Precautions

Talk to your doctor or pharmacist before using Sodium Alginate/Magnesium Alginate (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.

5. UNDESIRABLE EFFECTS OF SODIUM ALGINATE/MAGNESIUM ALGINATE (GAVISCON INFANT)?

Like all medicines, Sodium Alginate/Magnesium Alginate (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 Sodium Alginate/Magnesium Alginate (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. You can also report side effects directly via the Gaviscon Infoline 1800-10-8896292/ MMla: 8889-6292 or Email at: FeedbackPH@reckittbenckiser.com. By reporting side effects you can help provide more information on the safety of this medicine.

6. WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Other medicines and Sodium Alginate/Magnesium Alginate (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.

Sodium Alginate/Magnesium Alginate (Gaviscon Infant) with food and drink

Do not use Sodium Alginate/Magnesium Alginate (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 Sodium Alginate/Magnesium Alginate (Gaviscon Infant) to your child if you are not sure.

Sodium Alginate/Magnesium Alginate (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.

7. WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you forget to give Sodium Alginate/Magnesium Alginate (Gaviscon Infant):

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

8. SIGNS AND SYMPTOMS OF OVERDOSE

If your child takes more Sodium Alginate/Magnesium Alginate (Gaviscon Infant) than they should:

If your child takes too much Sodium Alginate/Magnesium Alginate (Gaviscon Infant) they may suffer from intestinal obstructions, be sick, lose their appetite, become irritable or tired and weak.

9. WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you accidentally give too much Sodium Alginate/Magnesium Alginate (Gaviscon Infant) ask your doctor or other healthcare professional for advice **immediately**.

10. HOW SHOULD YOU KEEP 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 sachet and carton after EXP(month/year).

Store at temperatures not exceeding 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.

11. WHEN SHOULD YOU CONSULT YOUR DOCTOR?

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



Manufacturer and Marketing Authorization Holder:
Manufactured by: Reckitt Benckiser Healthcare (UK)
Limited Dansom Lane, Hull HU8 7DS, United Kingdom
Imported by: Reckitt Benckiser Healthcare (Phils.) Inc.
3/F Mead Johnson Bldg., 2309 Don Chino Rocas Ave. Ext.,
Makati City, Philippines, 1231

HEALTH > HYGIENE > HOME

Questions or concerns:

Gaviscon Infoline 1800-10-8896292/ MMla: 8889-6292

Email at: FeedbackPH@reckittbenckiser.com

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.

Seek medical attention immediately at the first sign of any adverse drug reaction.

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