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GAVISCON INFANT

Magnesium alginate, Sodium alginate Powder for Oral Suspension 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
- 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.

this leaflet:

- What Gaviscon Infant is and what it is used for
- Before using Gaviscon Infant How to use Gaviscon Infant
- Possible side effects
- How to store Gaviscon Infant
- Further Information

1. What Gaviscon Infant is and what is it 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:

- if your baby was born pre-maturely
 - 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

Take special care with Gaviscon Infant:

If your baby is under one year, you should ask your doctor or pharmacist before giving

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

The maximum recommended daily dose of this medicinal product contains 287 mg sodium (found in table salt). This is equivalent to 14% of the adult recommended maximum daily dietary intake for sodium. To be taken into account by patients on a controlled sodium diet. Talk to your pharmacist or doctor if you need this product on a daily basis for a prolonged period of time, especially if you have been advised to have a

Gaviscon Infant should not be given to infants with kidney problems/damage or those on a low salt diet (see 'Do not use Gaviscon Infant').

3. How to use Gaviscon Infant

For infants aged 1 to 2 years. Not to be used in premature infants or infants under one vear except under medical supervision. Not suitable for children over 2 years, adults or

'Always use Gaviscon Infant exactly as described below. You should check with your doctor or pharmacist if you are not sure.

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

Infants under 4.5kg (10lb) – one sachet should be used

Infants over 4.5kg (10lb) – 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 115ml (4 fluid oz) of milk feed in the bottle
- Feed as normal

Breast fed infants and other infants up to 2 years of age:

- Mix each sachet with 5ml (1 teaspoon) of cooled, boiled water until a smooth paste is formed
- Add another 10ml (2 teaspoons) of cooled, boiled water
- 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 in 24 hours.

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

You **should not** use Gaviscon Infant for more than seven days without checking with your doctor or other health 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 and tired or weak.

If you accidentally give too much Gaviscon Infant ask your doctor or other health 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

Very rarely (less than 1 in 10,000) patients may experience constipation & diarrhoea. Side effects for which the frequency cannot be estimated from available data include hypersensitivity, bloating, discomfort of the stomach (gastric distension) and intestinal

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

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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. Further information

Each single dose sachet of Gaviscon Infant 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. Each carton contains 30 single dose sachets of powder,

Marketing Authorisation Holder and Manufacturer

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

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