Package leaflet: Information for the user

Gaviscon Liquid Sachets Oral Suspension Sodium alginate 500mg, Sodium bicarbonate 267mg, Calcium carbonate 160mg

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

This medicine is available without prescription. However, you will still need to take this medicine carefully to get the best results from it.

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 advice.

If you get 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 talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in the leaflet

- 1. What are Gaviscon Liquid Sachets and what are they used for?
- 2. What you need to know before taking Gaviscon Liquid Sachets
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1. What are Gaviscon Extra Liquid Sachets and what they are used for?

Gaviscon Liquid Sachets belongs to a group of medicines called "reflux suppressants", which act rapidly (in 3 minutes) to form a protective layer on top of the stomach contents for up to 4 hours to prevent stomach acid escaping from the stomach where it works into the food pipe causing pain and discomfort.

This medicine is used for the treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals or during pregnancy, or in patients with symptoms related to reflux oesophatitis.

2. What you need to know before you take Gaviscon Liquid Sachets

Do not take Gaviscon Liquid Sachets:

If you know that you are allergic (hypersensitive) to any of the ingredients of Gaviscon Liquid Sachets as very rarely difficulty in breathing and skin rashes have occurred (see further information for a full list).

Warnings and precautions

Take special care with Gaviscon Liquid Sachets

This medicine contains sodium (6.2 mmol per 10 ml) and calcium (1.6 mmol) per 10 ml. The maximum recommended daily dose of this medicinal product contains 1140.8 mg

sodium (found in table salt). This is the equivalent to 57.04% of the adult recommended maximum daily dietary intake for sodium.

Gaviscon Liquid Sachets are indicated for short term treatment only unless advised by your healthcare professional. Talk to your pharmacist or doctor if you need Gaviscon Liquid Sachets on a daily basis for a prolonged period of time or on a regular basis, especially if you have been advised to have a low salt diet.

Please also talk to your doctor regarding these salt contents if you suffer or have suffered from significant kidney or heart disease, as certain salts could interfere with these diseases.

If symptoms persist after 7 days, please consult your doctor.

Methyl parahydroxybenzoates (40 mg / 10 ml) and propyl parahydroxybenzoates (6 mg / 10 ml) may cause allergic reactions (possibly delayed).

Other medicines and Gaviscon Liquid Sachets

Do not take this medicine within two hours of taking other medicines by mouth as it can interfere with the action of some other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without prescription.

Pregnancy, breast-feeding and fertility:

You can take this product if you are pregnant or breast-feeding.

Important information about some of the ingredients of Gaviscon Liquid Sachets

This product contains methyl (E218) and propyl (E216) parahydroxybenzoates which may cause allergic reactions (possibly delayed).

3. How to take Gaviscon Liquid Sachets

For oral administration. Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults including the elderly and children 12 years and over: One to two sachets after meals and at bedtime, or as directed (up to four times a day).

Children under 12 years old: Should only be taken on medical advice.

If you take more Gaviscon Liquid Sachets than you should

If you take too much of this product you may feel bloated and experience some abdominal discomfort. Consult your doctor or pharmacist if this doesn't go away.

If you forget to take Gaviscon Liquid Sachets

If you forget a dose it is not necessary to double the dose next time, just carry on taking as before.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gaviscon Liquid Sachets can cause side effects although not everybody gets them.

If you experience these side effects, stop taking the product and consult your doctor immediately. Very rare (less than 1 in 10,000) chance of an allergic reaction to the ingredients. Symptoms of this may include skin rash, itching, difficulty breathing, dizziness or swelling of the face, lips, tongue or throat.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gaviscon Liquid Sachets

Keep this medicine out of the sight and reach of children. Do not use Gaviscon Liquid Sachets after the expiry date which is stated on the sachet and carton {EXP: month/year}. The expiry date refers to the last day of that month. Do not store above 25°C and store in the original package. Do not freeze or refrigerate.

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

What Gaviscon Liquid Sachets contains

The active substances in each sachet (10 ml) of oral suspension contains 500 mg sodium alginate, 267 mg sodium bicarbonate and 160 mg calcium carbonate. The other ingredients are carbomer, methyl (E214) and propyl (E216) parahydroxybenzoates, saccharin sodium, sodium hydroxide, natural mint flavour and purified water. This product does not contain sugar or colour.

What Gaviscon Liquid Sachets look like and contents of the pack

The medicinal product Gaviscon Liquid Sachets is an off-white suspension with the odour and flavour of peppermint.

Gaviscon Liquid Sachets are available in packs of 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 36 and 48 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

PA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24.

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

Export Distributors: Reckitt Coleman (Overseas) Limited, Hull, HU8 7DS.

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