Package leaflet: information for the user

Gaviscon Extra Chewable Tablets
Sodium alginate 250mg, Sodium bicarbonate 106.5mg, Calcium carbonate 187.5mg

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. 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 this leaflet

1. What Gaviscon Extra Chewable Tablets are and what they are used for?

Gaviscon Extra Chewable Tablets are a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate which works in two ways:

1. Neutralising excess stomach acid to relieve the pain and discomfort.
2. Forming a protective barrier of the stomach contents to soothe the burning pain in your chest which may last for up to 4 hours.

This medicine is used for the treatment of acid related symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion which may occur, for example, following meals or during pregnancy.

2. What you need to know before you take Gaviscon Extra Chewable Tablets

Do not take Gaviscon Extra Chewable Tablets if you know you are allergic to any of the ingredients of this medicine (listed in Section 4).

Talk to your doctor or pharmacist before using Gaviscon Extra Chewable Tablets if you

- Have severe kidney problems
- Have electrolyte disturbances causing low level of phosphate in the blood (hypophosphatemia).
- Suffer or have suffered from significant kidney or heart disease as certain salts could interfere with these diseases (talk to your doctor regarding the salt content)
- Know you have reduced amounts of gastric acid in your stomach, as this product may be less effective.

As with other antacid products, taking Gaviscon Extra Chewable Tablets can mask the symptoms of other more serious, underlying medical conditions.
If symptoms persist after 7 days consult your doctor.

Children
Do not give this medicine to a child under 12 years of age except on the advice of a doctor. There is a risk of increased levels of sodium in the blood (hypernatremia) in children who have kidney problems or who have an inflamed stomach or bowel (gastroenteritis).

Other medicines and Gaviscon Extra Chewable Tablets
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 obtained without prescription.

Pregnancy, breast-feeding and fertility:
You can take this product if you are pregnant or breast-feeding or planning to have a baby. As with all medicines, the treatment duration should be limited as much as possible.

Important information about some of the ingredients of Gaviscon Extra Chewable Tablets
This medicine contains 5.86 mg of aspartame in each tablet. Aspartame is broken down into phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

These tablets contain carmoisine lake (E122) which may cause an allergic reaction.

They also contain 55.89 mg (2.43 mmol) sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

The maximum recommended daily dose of this medicinal product contains 894.24 mg sodium (found in table salt). This is equivalent to 44.71% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Gaviscon Extra Chewable Tablets on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

They also contain 75 mg (1.88 mmol) calcium per tablet.

If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

Speak to a doctor before taking this medicine if you have kidney stones or high levels of calcium in your blood.

3. How to take Gaviscon Extra Chewable Tablets

Always use this medicine 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 oral administration, chew thoroughly before swallowing.

Adults including the elderly and children 12 years and over:
When symptoms occur take two to four tablets after meals and at bedtime up to four times a day.
Children under 12 years old:
Should only be taken on medical advice.

If you take more Gaviscon Extra Chewable Tablets than you should:
If you take too much of this product it is unlikely to cause you any harm. However, you may feel bloated. Consult your doctor if this doesn't go away.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gaviscon Extra Chewable Tablets 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 abdominal pain, diarrhoea, nausea, vomiting, skin rash, itching, difficulty breathing, dizziness or swelling of the face, lips, tongue or throat and difficulty in breathing.

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 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 Extra Chewable Tablets

Keep this medicine out of the sight and reach of children.
Do not use this product after the expiry date which is stated on the carton after EXP (month/year). The expiry date refers to the last day of that month.
Do not store above 30^{o}C (25^{o}C for the handypack) and store in the original package to protect from moisture.
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 further information

What Gaviscon Extra Chewable Tablets contains
The active substances in each chewable tablet are 250mg sodium alginate, 106.5mg sodium bicarbonate and 187.5mg calcium carbonate. The other ingredients are xylitol, carmellose sodium, magnesium sterate, macrogol 20,000, mannitol (E421), copovidone, acesulfame-k, aspartame (E951), mint flavour and carmoisine lake (E122). This product does not contain gluten.

What Gaviscon Extra Chewable Tablets look like and contents of the pack
Gaviscon Extra Chewable Tablets are flat, circular, bi-layer tablets with the odour and flavour of peppermint. One layer of the tablet is coloured pin with a slightly mottled appearance, with the other layer being white.
Gaviscon Extra Chewable Tablets are available in packs of 4, 6, 8, 10, 12, 16, 24, 32, 48, 60, 62, 64 and 80. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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