

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Gaviscon Extra Mixed Berries Chewable Tablets

Sodium alginate 250 mg, Sodium hydrogen carbonate 106.5 mg, Calcium carbonate 187.5 mg

**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 are Gaviscon Extra Mixed Berries Chewable Tablets and what are they used for?
2. What you need to know before taking Gaviscon Extra Mixed Berries Chewable Tablets.
3. How to take Gaviscon Extra Mixed Berries Chewable Tablets.
4. Possible side-effects.
5. How to store Gaviscon Extra Mixed Berries Chewable Tablets.
6. Contents of the pack and further information.

### **1. WHAT ARE GAVISCON EXTRA MIXED BERRIES CHEWABLE TABLETS AND WHAT ARE THEY USED FOR?**

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

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

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

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GAVISCON EXTRA MIXED BERRIES CHEWABLE TABLETS**

#### **Do not take this medicine if:**

- you know you are allergic to any of the ingredients of this medicine (listed in section 6).

#### **Warnings and precautions:**

#### **Talk to your doctor or pharmacist before using this medicine if you:**

- 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).
- Have been told by your doctor that you have an intolerance to some sugars.
- Have **severe kidney problems**.
- Have electrolyte disturbance causing **low level of phosphate** in the blood (hypophosphatemia).
- Know you have reduced amounts of gastric acid in your stomach, as this product may be less effective.

As with other antacid products, taking this medicine 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. There is a risk of increased levels of sodium in the blood (hyponatremia) in children who have kidney problems or who have an inflamed stomach or bowel (gastroenteritis).

### **Other medicines and Gaviscon Extra Mixed Berries Chewable Tablets:**

Do not take this product within two hours of taking other medicines by mouth as it can interfere with the action of some other medicines. This is especially important if you are taking antihistamines, antibiotics (tetracyclines and quinolones such as norfloxacin), iron preparation, thyroid hormones, antifungals such as ketoconazole, digoxin and beta-blockers (for heart conditions), neuroleptics (for mental illness), thyroxine, chloroquine (for malaria), bisphosphonates (for osteoporosis) and estramustine (for prostate cancer).

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 this medicine:**

This medicine contains 5.86 mg aspartame (E951) in each chewable tablet. Aspartame is a source of 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 chewable tablets contain carmoisine lake (E122) which may cause an allergic reaction.

They also contain 223.7 mg (9.728 mmol) sodium per four chewable tablet dose. The maximum recommended daily dose of this medicinal product contains 895 mg sodium (found in table salt). This is equivalent to 44.75% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you need this medicine 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 300 mg (7.5 mmol) calcium per four chewable tablet dose. Speak to a doctor before taking this medicine if you have kidney stones or high levels of calcium in your blood.

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

## **3. HOW TO TAKE GAVISCON EXTRA MIXED BERRIES 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 and children 12 years and over:** When symptoms occur take two to four chewable tablets after meals and at bedtime, up to four times a day.

**Children under 12 years old:** Treatment of children younger than 12 years of age is not recommended.

**If you take more of this medicine than you should:** If you take too much of this product it is unlikely to cause you any harm. However, you may feel bloated and experience some abdominal discomfort. Consult your doctor if this doesn't go away.

**If you forget to take this medicine:** If you forget a dose, do not double the dose next time, just carry on taking as before.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Gaviscon Extra Mixed Berries 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 (may affect up to 1 in 10,000 people) chance of an allergic reaction to the ingredients. Symptoms of this may include abdominal pain, diarrhoea, nausea, vomiting, skin rash, itching, dizziness, swelling of the face, lips, tongue or throat and difficulty in breathing.

Ingestion of large quantities of calcium carbonate, a component of this product, may cause an increase in blood pH (alkalosis), too much calcium in the blood (hypercalcaemia), increased secretion of stomach acid, and constipation. These usually occur following larger than recommended dosages.

#### **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. Website: [www.hpra.ie](http://www.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 and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. CONTENTS OF THE PACK AND FURTHER INFORMATION**

##### **What this medicine contains:**

The active substances in each chewable tablet are 250 mg sodium alginate, 106.5 mg sodium hydrogen carbonate and 187.5 mg calcium carbonate. The other ingredients are xylitol, carmellose sodium, magnesium stearate, macrogol, mannitol (E421), copovidone, acesulfame-potassium, aspartame (E951), cranberry flavour, raspberry flavour, fruit flavour and carmoisine lake (E122). Flavours contain propylene glycol (E1520) and sucrose.

**What this medicine looks like and the contents of the pack:**

Flat, circular, bi-layer chewable tablets with the odour and flavour of mixed berry. One layer of the chewable tablet is coloured pink with a slightly mottled appearance with GDB surface markings, with the other layer being white with sword and circle surface markings.

This medicine is available in packs of 4, 6, 8, 12, 16, 24, 32, 48, 60, 64, 80 and 112 chewable tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

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

**Manufacturers:**

RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

**This medicinal product is authorised in the member states of the EEA under the following names:**

TBC

**This leaflet was approved in Upon approval**