

PACKAGE INFORMATION LEAFLET FOR THE USER

**GAVISCON DOUBLE ACTION MIXED BERRIES
FLAVOUR ORAL SUSPENSION**

Sodium alginate, Sodium hydrogen carbonate, Calcium carbonate.

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.
- **You must contact a doctor if your symptoms worsen or do not improve after 7 days.**
- 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.

What is in this leaflet

1. What Gaviscon Double Action Mixed Berries Flavour Oral Suspension is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information.

1) What Gaviscon Double Action Mixed Berries Flavour Oral Suspension is and what it is used for

Gaviscon Double Action Mixed Berries Flavour Oral Suspension is a combination of two antacids (Calcium carbonate and Sodium hydrogen carbonate) and an alginate and works in two ways:

1) Neutralising excess stomach acid to relieve the pain and discomfort.

2) Forming a protective barrier over the stomach contents to soothe the burning pain in your chest which may last for up to four hours.

Gaviscon Double Action Mixed Berries Flavour Oral Suspension is used for the treatment of acid-related symptoms of gastro-oesophagus 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 this medicine:

Do not take this medicine if:

- You know you are allergic (hypersensitive) to any of the ingredients (see section 6 for a full list of ingredients).

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.
- 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 more serious, underlying medicine 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 (hyponatremia) in children who have kidney problems or who have an inflamed stomach or bowel (gastroenteritis).

Other medicines and Gaviscon Double Action Mixed Berries Flavour Oral Suspension:

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 (tetracycline and quinolones such as norfloxacin), iron preparations, antifungals such as Ketoconazole, digoxin and beta-blockers (for heart conditions), neuroleptics (for mental illness), thyroxine, chloroquines (for malaria) and biphosphates (for osteoporosis). 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 medicine 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 Double Action Mixed Berries Flavour Oral Suspension

This product contains methyl (E218) and propyl (E216) parahydroxybenzoates which may cause allergic reactions (possibly delayed). It also contains 127.88 mg (5.56 mmol) sodium per 10ml dose (main component of cooking/table salt) This is equivalent to 6.4 % of the recommended maximum daily dietary intake of sodium for an adult.

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The maximum recommended daily dose of this medicinal product contains 1023 mg sodium (found in table salt). This is equivalent to 51.15% 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. It also contains 130mg (3.25 mmol) calcium per dose. Speak to a doctor before taking this medicine if you have kidney stones or high levels of calcium in your blood.

This medicine contains 21.38 mg propylene glycol in each 10 ml.

Driving and using machines

This medicine has no influence on the ability to drive and use machines.

3) How to take this medicine

Always take 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. Check that the cap seal is unbroken before first using this product. For oral use. Shake well before use.

Adults, including the elderly and children over 12 years: Take 10 - 20ml (two to four 5ml spoonfuls) 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 Double Action Mixed Berries Flavour Oral Suspension than you should:

If you take too much of this product you may feel bloated. It is unlikely to cause you any harm, but please consult your doctor or pharmacist if this doesn't go away.

If you forget to take Gaviscon Double Action Mixed Berries Flavour Oral Suspension:

It is not necessary to double the dose next time, just carry on taking as before. **If symptoms persist after 7 days consult your doctor.**

4) Possible side-effects:

Like all medicines, Gaviscon Double Action Mixed Berries Flavour Oral Suspension 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 rarely (less than 1 in 10,000) chance of an allergic reaction from 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.

Reporting 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 yellow card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store this medicine

• Keep out of the sight and reach of children • Do not use this product after the expiry date (EXP: month/year) shown. The expiry date refers to the last day of that month • Use within 6 months of opening • Do not store above 30 C. Do not refrigerate or freeze.

• Check the cap seal is unbroken before first using this product. 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 this medicine contains: Each 10ml of oral suspension contains 500mg sodium alginate, 213mg sodium bicarbonate and 325mg calcium carbonate as the active ingredients. The other ingredients are carbomer, methyl (E218) and propyl (E216) parahydroxybenzoates, sodium saccharin, sodium, propylene glycol (present in cranberry, raspberry and fantasy fruit flavours), sodium hydroxide and purified water. This product does not contain sugar or gluten.

What this medicine looks like and contents of the pack:

This medicine is an off-white to cream suspension with the odour and flavour of berry. Gaviscon Double Action Mixed Berries Flavour Oral Suspension is available in bottles of 150ml, 200ml, 250ml, 300ml, and 600ml. Not all sizes may be marketed.

Marketing Authorisation Holder and Manufacturer: Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS. Gaviscon is a trade mark of the Reckitt group.

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