

PACKAGE LEAFLET INFORMATION FOR THE USER
Gaviscon Double Action Mixed Berries Flavour Chewable Tablets.
Sodium alginate, sodium hydrogen carbonate and 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.
- 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 Double Action Mixed Berries Flavour Chewable Tablets and what are they used for?
2. What you need to know before taking Gaviscon Double Action Mixed Berries Flavour Chewable Tablets?
3. How to take Gaviscon Double Action Mixed Berries Flavour Chewable Tablets?
4. Possible side-effects.
5. How to store Gaviscon Double Action Mixed Berries Flavour Chewable Tablets?
6. Contents of the pack and further information.

1. WHAT ARE GAVISCON DOUBLE ACTION MIXED BERRIES FLAVOUR CHEWABLE TABLETS AND WHAT ARE THEY USED FOR?

Gaviscon Double Action Mixed Berries Flavour Chewable Tablets are a combination of two antacids (calcium carbonate and sodium hydrogen carbonate) and an alginate and work 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.

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 DOUBLE ACTION MIXED BERRIES FLAVOUR CHEWABLE TABLETS:

Do not take Gaviscon Double Action Mixed Berries Flavour 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 Double Action Mixed Berries Flavour Chewable Tablets if you:

- have **severe kidney problems**
- have electrolyte disturbance 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 Double Action Mixed Berries Flavour 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 (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 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 Double Action Mixed Berries Flavour Chewable Tablets

This medicine contains 5.86 mg aspartame in each 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.

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Contains carmoisine lake (E122) which may cause an allergic reaction. They also contain 55.89 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2.8 % of the recommended maximum daily dietary intake of sodium for an adult. 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 doctor or pharmacist if you need this product on a daily basis for a prolonged period of time, especially if you have been advised to follow a low salt (sodium) diet. This medicine also contains 300 mg (7.5 mmol) calcium per 4 table 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 Mannitol which may have a mild laxative effect.

They also contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

3. HOW TO TAKE GAVISCON DOUBLE ACTION MIXED BERRIES FLAVOUR 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: 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 Double Action Mixed Berries Flavour 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 Double Action Mixed Berries Flavour Chewable Tablets

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 Double Action Mixed Berries Flavour 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.

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 the internet at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. HOW TO STORE GAVISCON DOUBLE ACTION MIXED BERRIES FLAVOUR 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°C 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 Double Action Mixed Berries Flavour Chewable Tablets contain

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 20,000, mannitol (E421), copovidone, acesulfame-K, aspartame (E951), cranberry flavour, raspberry flavour, fantasy fruit flavour, Potassium and carmoisine lake (E122). The flavours contain sucrose.

This product does not contain gluten.

What Gaviscon Double Action Mixed Berries Flavour Chewable Tablets look like and the contents of the pack

Gaviscon Double Action Mixed Berries Flavour Chewable Tablets are flat, circular, bi-layer tablets with the odour and flavour of berry.

One layer of the tablet is coloured pink with a slightly mottled appearance, with the other layer being white.

Gaviscon Double Action Mixed Berries Flavour Chewable Tablets are available in packs of 4, 6, 8, 12, 16, 24, 32, 48, 60, 62, 64 and 80 chewable tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Reckitt Benckiser Healthcare (UK) Ltd, Hull, HU8 7DS
 Marketing Authorisation Number
 PL 00063/0755

This leaflet was last approved in 09/2020.

3191388

RB Artwork and Print Specification

Trident Reference No:	RB443026
ZEN Ref:	TR2018393
Action:	B
Brand:	Gaviscon
Category:	Adult
Segment Group:	Double Action Tablets
Segment:	Mixed Berries
Pack Size:	12 24 48Pack
Market/Country:	UK
Date:	24/02/21

RBH Contact: Anoop James

Artwork Type: BW Commercial

Component Code (if applicable):	3191388
2 nd Component Code (if applicable):	N/A
Parent Technical Packaging Specification:	D0064065
Finished Goods Code:	3065907
Supply Point:	RB Hull
3rd Party Code:	N/A
Pharmacode No/NE:	101000103
Edgemark Position:	N/A

CAD Cam Ref:	G-Lit-D0064065-175x200mm
Printer:	Medica Packaging Limited (Crewe, UK)
Substrate:	Paper White

Technical & Non-Printing Items	
Cutter	Cutter 2 (if applicable)
Guides	Guides 2 (if applicable)

Colours (Leaflet)	
Process Black	T
LT	B

BARCODE INFO

Barcode Type:	N/A
Barcode Number:	N/A
Magnification:	N/A
Truncated By:	N/A
Full Height:	N/A
Bar Height (Smallest Bar):	N/A
BWR:	N/A
Encoded Data:	N/A



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CUSTOMER INFO:
 Minimum Point Size = 9.00pt



Production line		
Manufacturing site		
Pack Tech approver	1st 2nd	
Date		
Check Criteria	Details & Comments	Checks
Approvals		1st 2nd
Market Approval		
Regulatory Approval		
3rd Party Approval		
Technical Drawing/ Cutter ref no. & PPI component code		
PPI component code number/s correct on artwork?		
PPI component code number/s in correct position on artwork?		
Correct drawing for the production line?		
Profile shape & dimensions		
Graphics layout/orientation		
Unwind diagram (PPTD1022/1-20)		
Printable areas/bleed		
Varnish free areas		
Variable coding position & dimensions		
Varnish and print requirements		
Pre-printed headers (alignment and suitability)		
Embossing, Braille & Foil Blocking		
Separations on artwork		
Alignment within cutter		
Braille structure		
Verification Code Type; Pharma Code / 2D / OCV		
Bar sequence and/or number correct on artwork?		
Bar sequence and/or number in correct position on artwork?		
Size (height, width, spacing, font)		
Direction of read		
Light margins and print free areas		
Colour		
Repeat distance (reeled material)		
Cross check related docs ie BOM		
Bar code Type; EAN, ITF, Code39, etc		
Magnification / width and height		
Colour (e.g. black print on white background)		
Light margins & indicators		
Bearer bars & H gauges (if required)		
Symbol grade (Pass = A,B,C; Action = D,F)		
Bar code number (human readable)		
Bar code number (encoded & hidden data)		
Confirm bar code number from source		
Cross check related docs (JDE/PID)		
Photo-electric cell mark / edge marks		
Present & per Tech drawing?		
Correct pitch?		
Additional markings		
e-mark, recycle logo etc		
Legend box (RB specification)		
Correct component code		
Correct D spec / has cutter changed?		
Correct printer / has printer changed?		
Correct Substrate		
A/W is set up appropriately for this substrate		
Edge mark details		
Pharmacode details		
Colours & print process		
Varnish		
Barcode information		
General details are correct		
Pass / Fail comments and Signature		
By approving the artwork referenced within this form I authorise it for release to the print supplier		
Additional Comments		

RB Artwork and Print Specification

Trident Reference No: RB443026
 ZEN Ref: **TR2018393**
 Action: **B**
 Brand: Gaviscon
 Category: Adult
 Segment Group: Double Action Tablets
 Segment: Mixed Berries
 Pack Size: 12 24 48Pack
 Market/Country: UK
 Date: 24/02/21

RBH Contact: Anoop James

Artwork Type: **BW Commercial**

Component Code (2D if applicable): **3191388**
 2nd Component Code (if applicable): **N/A**
 Parent Technical Packaging Specification: D0064065
 Finished Goods Code: **3065907**
 Supply Point: RB Hull
 3rd Party Code: N/A
 Pharmacode No/NE: 101000(103)
 Edgemark Position: N/A

CAD Cam Ref: G-Lit-D0064065-175x200mm
 Printer: Medica Packaging Limited (Crewe, UK)
 Substrate: Paper White

Technical & Non Printing Items
 Cutter Cutter 2 (if applicable)
 Guides Guides 2 (if applicable)

Colours (Leaflet)
 Process Black

BARCODE INFO

Barcode Type: N/A
 Barcode Number: N/A
 Magnification: N/A
 Truncated By: N/A
 Full Height: N/A
 Bar Height (Smallest Bar): N/A
 BWR: N/A
 Encoded Data: N/A



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