200mm

Pharmacode Reads This Way

First Bar Last Bar

175mm

PG1

SCHEDULING STATUS S0

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

GAVISCON DOUBLE ACTION TABLETS.

Chewable tablet. Each tablet contains sodium alginate 250 mg, sodium bicarbonate 106,5 mg and calcium carbonate 187,5 mg.

Read all of this leaflet carefully because it contains important information for you

GAVISCON DOUBLE ACTION TABLETS is available without a doctor's prescription, for you to treat a mild illness. You need to use GAVISCON DOUBLE ACTION TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Do not share GAVISCON DOUBLE ACTION TABLETS with any other person
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

1. WHAT GAVISCON DOUBLE ACTION TABLETS CONTAINS

- The active substances are sodium alginate 250 mg, sodium bicarbonate 106,50 mg and calcium carbonate 187,50 mg.
- The other ingredients are mannitol, macrogol 20,000, copovidone, coolmint flavour, carmoisine lake, xylitol and magnesium stearate.
- Contains sweeteners: (Acesulfame k 5,863 mg and Aspartame 5,863 mg per tablet)

2. WHAT GAVISCON DOUBLE ACTION TABLETS IS USED FOR

GAVISCON DOUBLE ACTION TABLETS relieves symptoms of heartburn and indigestion.
It works by reacting with saliva and stomach acid to make a viscous gel that floats on top of the stomach contents.

3. BEFORE YOU TAKE GAVISCON DOUBLE ACTION TABLETS

Do not take GAVISCON DOUBLE ACTION TABLETS:

If you are hypersensitive (allergic) to any of the ingredients.
If you have phenylketonuria (a genetic disorder when the body cannot process the amino acid phenylalanine).

Take special care with GAVISCON DOUBLE ACTION TABLETS:

- If you have heart disease or high blood pressure – GAVISCON DOUBLE ACTION TABLETS contains sodium (salt) and may worsen heart disease or high blood pressure.
- If you have kidney disease, electrolyte imbalances (e.g. low calcium).
- If you have been told by your doctor that you have low levels of stomach acid.
- If you have cirrhosis of the liver.
- If you are taking steroids.

If you have kidney problems, you are prone to develop high levels of calcium in the blood and increased secretion of stomach acid, when taking high doses of GAVISCON DOUBLE ACTION TABLETS.
Prolonged use of Gaviscon Double Action Tablets should be avoided.
If symptoms do not improve after seven days, please consult your doctor.
As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions.

Taking GAVISCON DOUBLE ACTION TABLETS with food and drink:

GAVISCON DOUBLE ACTION TABLETS is usually taken after meals and at bedtime.
Do not take GAVISCON DOUBLE ACTION TABLETS with large amounts of milk or milk-products.
To do so may increase the risk of side-effects.

Pregnancy and breast-feeding:

No effects of GAVISCON DOUBLE ACTION TABLETS have been shown in breast fed newborns/infants of treated mothers. Gaviscon Double Action Tablets can be used during breastfeeding.
If you are pregnant or breast-feeding, please consult your doctor, pharmacist or other health care professional for advice before taking GAVISCON DOUBLE ACTION TABLETS.
Fertility: Clinical Data do not suggest that Gaviscon Double Action Tablets has an effect on human fertility.

Driving and using machinery:

GAVISCON DOUBLE ACTION TABLETS *has no or negligible influence on driving or the ability to operate tools or machines.*

Taking other medicines with GAVISCON DOUBLE ACTION TABLETS:

Always tell your healthcare professional if you are taking any other medicine.

GAVISCON DOUBLE ACTION TABLETS may affect the absorption of other oral medicines.

A time interval of 2 hours should be considered between GAVISCON DOUBLE ACTION TABLETS intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, concomitant use of GAVISCON DOUBLE ACTION TABLETS may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE GAVISCON DOUBLE ACTION TABLETS

Chew tablets thoroughly. Do not swallow the tablets whole.
Always take GAVISCON DOUBLE ACTION TABLETS exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.
Adults and children 12 years and over: Two to four tablets after meals and at bedtime
Children under 12 years: Not recommended.
Elderly: The same dose as indicated for adults.-
If you have the impression that the effect of GAVISCON DOUBLE ACTION TABLETS is too strong or too weak, tell your doctor or pharmacist.
Do not share medicines prescribed for you with any other person.

If you take more GAVISCON DOUBLE ACTION TABLETS than you should:

Excessive doses may cause bloating.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take GAVISCON DOUBLE ACTION TABLETS:

If you miss a dose of GAVISCON DOUBLE ACTION TABLETS, take it as soon as you remember. Take any remaining doses for that day at evenly spaced intervals. Do not double the dose to make up for the forgotten doses.

5. POSSIBLE SIDE-EFFECTS

GAVISCON DOUBLE ACTION TABLETS can have side-effects.
Not all side-effects reported for GAVISON DOUBLE ACTION TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GAVISCON DOUBLE ACTION TABLETS, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following side effects occur, speak to your doctor immediately:

Stomach cramps, flatulence, constipation.
Skin rash, hives, itching, and problems with breathing.

6. STORING AND DISPOSING OF GAVISCON DOUBLE ACTION TABLETS

Store all medicines out of reach of children.
Blister – store at or below 30 ° C. Store in a carton until required for use.
Flip-top – store at or below 25 ° C. Use within 3 months of opening.
Do not use the product after the expiry date shown on the carton, label or blister strip.
Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION

Cartons containing 8 and 24 tablets in blisters with aluminium foil lidding or turquoise coloured, polypropylene container with flip-top lid containing 12 tablets.

8. IDENTIFICATION

A flat circular (15,0 mm diameter), bi-layered tablet with bevelled edges, pink and slightly mottled with sword and circle on the observe and white with "GDA250" on the reverse, and an odour of mint.

9. REGISTRATION NUMBER

42/11.10/0263

10. NAME, BUSINESS ADRESS AND TELEPHONE NUMBER OF THE HOLDER OF REGISTRATION CERTFICATE

Reckitt Benckiser Pharmaceuticals (Pty) Ltd
8 Jet Park Road
Elandsfontein, 1601
+2711 871 1611

11.DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date on the registration certificate:
14 September 2012
Date of the most recently revised patient information leaflet: 20 December 2019

Please go to the link for access to the corresponding PI:
https://cpdcentre.co.za/product-inserts/Gaviscon-Double-Action-Tablet.pdf

Namibia	18/11.4/0106 (NS0)
Malawi	PMPB/PL485/10 (GS)
Zambia	133/025 (P)
Mauritius	R12211/02/14
Zimbabwe	2017/16.1/5473 (HR)

3158556

200mm

PG1

SKEDULERINGSTATUS S0

EIENDOMSNAAM, STERKTE EN DOSERINGS VORM

GAVISCON DOUBLE ACTION TABLETS.

Koubare tablet. Elke tablet bevat natriumalginaat 250 mg, natriumbikarbonaat 106, 5 mg en kalsiumkarbonaat 187, 5 mg.

Lees hierdie hele pamflet noukeurig deur want dit bevat belangrike inligting vir u.

GAVISCON DOUBLE ACTION TABLETS is beskikbaar sonder 'n voorskrif van 'n dokter, vir jou om matige siektes te behandel. U moet GAVISCON DOUBLE ACTION TABLETS versigtig gebruik om die beste resultate daaruit te kry.

- Bewaar hierdie pamflet. Dit mag nodig wees om dit weer te lees.
- Vra u apteker indien u meer inligting of advies benodig.
- Moenie GAVISCON DOUBLE ACTION TABLETS met enige ander persoon deel nie.
- Sien u dokter indien u simptome vererger of na 7 dae nie verbeter nie.

1. WAT GAVISCON DOUBLE ACTION TABLETS BEVAT

Die aktiewe middels is natriumalginaat 250 mg, natriumbikarbonaat 106,50 mg en kalsiumkarbonaat 187,50 mg.
Die ander bestanddele is mannitol, makrogol 20.000, kopovidoon, koelmintgeur, karmoisienmeer, xylitol en magnesiumstearaat.
Bevat versoeter (Acesulfame K 5,863 mg and Aspartaam 5,863 mg per tablet).

2. WAARVOOR GAVISCON DOUBLE ACTION TABLETS GEBRUIK WORD

GAVISCON DOUBLE ACTION TABLETS verlig simptome van sooibrand en slegte spysvertering.
Dit werk deur 'n reaksie met speeksel en maagsuur om 'n viskose jel te maak wat bo-op die maaginhoud dryf.

3. VOOR U GAVISCON DOUBLE ACTION TABLETS NEEM

Moet nie GAVISCON DOUBLE ACTION TABLETS gebruik nie:

Indien jy hipersensitief (allergies) is vir enige van die bestanddele nie.
Indien jy fenielketonurie ('n genetiese afwyking wat veroorsaak dat die liggaam nie aminosuure fenielalanien kan verwerk nie) het nie.

Wees veral versigtig met GAVISCON DOUBLE ACTION TABLETS:

- Indien jy 'n hartsiekte of hoë bloeddruk het - **GAVISCON DOUBLE ACTION TABLETS**
- bevat natrium (sout) en mag hartsiekte of hoë bloeddruk vererger.
- Indien jy 'n niersiekte of elektrolietwanbalans (bv. lae kalsium) het.
- Indien jy deur jou dokter ingelig is dat jy lae vlakke van maagsuur het.
- Indien jy sirrose (komplikasies met of lewersiekte) het
- Indien jy steroïdes neem.

Indien jy nierprobleme het, is jy geneig om hoë vlakke van kalsium in die bloed en 'n verhoogde afskeiding van maagsuur te ontwikkel indien u hoë vlakke van GAVISCON DOUBLE ACTION TABLETS inneem.
Langdurige gebruik van GAVISCON DOUBLE ACTION TABLETS moet vermy word.
Indien simptome nie na sewe dae verbeter nie, raadpleeg asseblief u dokter.
Soos met ander teensuurmiddels, kan die gebruik van hierdie produk die simptome van ander ernstige, onderliggende mediese toestande masker.

Die neem van GAVISCON DOUBLE ACTION TABLETS met spys en drank:

GAVISCON DOUBLE ACTION TABLETS word gewoonlik geneem na maaltye en met slapenstyd.
Moet nie GAVISCON DOUBLE ACTION TABLETS neem met 'n groot aantal melk of melk produkte nie, dit mag die risiko van newe-effekte verhoog.

Swangerskap en borsvoeding:

Geen newe-effekte van GAVISCON DOUBLE ACTION TABLETS is getoon in pasgebore babas/suigelinge van behandelde moeders nie.
Gaviscon Double Action Tablette kan gebruik word tydens borsvoeding.
Indien u swanger is of u baba borsvoed, raadpleeg u dokter, apteker of ander professionele gesondheidswerker vir advies voor die neem van Gaviscon DOUBLE ACTION TABLETS.
Vrugbaarheid:
Kliniese data dui nie daarop dat Gaviscon Double Action tablette 'n invloed op die vrugbaarheid van mense het nie.

Bestuur en gebruik van masjinerie:

Gaviscon Double Action Tablette het geen of 'n onbeduidende invloed op die vermoë om te bestuur of die vermoë om werktuie of masjinerie te beheer nie.

Die gebruik van ander medisyne saam met GAVISCON DOUBLE ACTION TABLETS:

Lig altyd u mediese dokter in as u enige ander medisyne neem.
GAVISCON DOUBLE ACTION TABLETS mag die opname van baie ander orale medisyne beïnvloed.

'n tydsinterval van 2 ure behoort oorweeg te word na die inname van GAVISCON DOUBLE ACTION TABLETS en die inna,e van enige ander medisinale produkte, veral tetrasikliene, fluorokinolone, ystersoute, skildklierhormone, chloorkien, bisfosfonate en estramustien.
As u op 'n gereelde basis ander medisyne neem, insluitend aanvullende of tradisionele medisyne, kan die gelyktydige gebruik van GAVISCON DOUBLE ACTION TABLETS ongewensde interaksies veroorsaak.
Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies.

4. HOE OM GAVISCON DOUBLE ACTION TABLETS TE GEBRUIK

Kou die tablette deeglik. Moet nie die tablette heel sluk nie.
Neem altyd GAVISCON DOUBLE ACTION TABLETS presies soos in die pamflet beskryf word, of soos deur u dokter, apteker of verpleegkundige aanbeveel is. Raadpleeg u dokter, apteker of verpleegster as u nie seker is nie.
Volwassenes en kinders 12 jaar en ouer: twee tot vier tablette na maaltye en met slapenstyd.
Kinders jonger as 12 jaar: Nie aanbeveel nie.
Bejaardes: Dieselfde dosis soos aangedui vir volwassenes.
Indien u die indruk kry dat die effekte van GAVISCON DOUBLE ACTION TABLETS té sterk of té swak is, raadpleeg u dokter of apteker.
Moet nie medisyne wat aan u voorgeskryf is, deel met enige ander persoon nie.

Indien jy meer GAVISCON DOUBLE ACTION TABLETS inneem as wat jy behoort:

Oorgroot dosisse mag opgeblasenheid veroorsaak.
In die geval van oordosering, raadpleeg u dokter of apteker. Indien daar nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om GAVISCON DOUBLE ACTION TABLETS te neem:

As u 'n dosis van GAVISCON DOUBLE ACTION TABLETS mis, neem dit sodra u onthou. Neem enige oortollige dosisse vir die dag in eweredige intervalle. Moenie 'n dubbele dosis neem om op te maak vir die vergete dosis nie.

5. MOONTLIKE NEWE-EFFEKTE

GAVISCON DOUBLE ACTION TABLETS kan newe-effekte hê.
Nie alle newe-effekte wat vir GAVISCON DOUBLE ACTION TABLETS aangemeld word, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of as u enige probleme ervaar tydens die gebruik van GAVISCON DOUBLE ACTION TABLETS, raadpleeg u dokter, apteker of ander professionele gesondheidswerker vir advies.

Indien enige van die volgende newe-effekte plaasvind, raadpleeg u dokter dadelik:

Maagkrampe, winderigheid, hardlywingheid.
Veluitslag, galbulte, jeukerigheid, probleme met asemhaling.

6. BERGINGSAANWYSINGS EN VERWYDERING VAN GAVISCON DOUBLE ACTION TABLETS

Hou alle medisyne buite die bereik van kinders.
Stulpstrook - Bewaar teen of benede 30 ° C. Hou in karton tot nodig vir gebruik.
Klep-deksel - Bewaar teen of benede 25 ° C. Gebruik binne 3 maande na produk oopgemaak is.
Moet nie die produk gebruik na verloop van die vervaldatum wat op die karton, etiket of stulpstrook aangedui word nie.
Besorg alle ongebruikte medisyne terug aan u apteker.
Moet nie wegdoen met ongebruikte medisyne in dreine en rioolstelsels (bv. Toilette) nie.

7. AANBIEDING

Karton wat bevat 8 en 24, tablette in stulstroke, met aluminiumfoeliebedekking of turkoois gekleurde, polipropileen houer met 'n klep-deksel wat 12 tablette bevat.

8. IDENTIFIKASIE

'n plat sirekelvormige (15,0 mm deursnee), tweelaagse tablet met afgeskuinste kante, pienk en effens gevlek met swaard en sirkel op die voorkant en wit met "GDA250" aan die agterkant, en 'n kruisementagtige reuk.

9. REGISTRASIE NOMMER

42/11.10/0263

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

Reckitt Benckiser Pharmaceuticals (Pty) Ltd
8 Jet Park Road
Elandsfontein, 1601
+2711 871 1611

11. DATUM VAN PUBLIKASIE VAN DIE PASIËNT-INLIGTINGSVOUBILJET

Datum op die registrasiesertifikaat:
14 September 2012
Datum op die mees onlangste pasiënt-inligtingsvoubiljet: 20 Desember 2019

Gaan asseblief na die web adres vir die ooreenstemmende professionele informasie:
https://cpdcentre.co.za/product-inserts/Gaviscon-Double-Action-Tablet.pdf

3158556

175mm

CUSTOMER INFO:
Minimum Point Size = 8.00pt

RB Artwork and Print Specification

Trident Reference No:	RB430610
ZEN Ref:	**TR1936640**
Action:	**D**
Brand:	Gaviscon
Category:	Adult
Segment Group:	Double Action Tablets
Segment:	Peppermint
Pack Size:	4x6x24Tablets
Market/Country:	South Africa
Date:	20/07/20
RBH Contact:	Shivesh Patel

Artwork Type: BW Commercial

Component Code (2D if applicable):	**3158556**
2nd Component Code (if applicable):	**N/A**
Parent Technical Packaging Specification:	D0064065
Finished Goods Code:	**8065348 8063678**
Supply Point:	RB Hull
3rd Party Code	N/A
Pharmacode No/NE:	1100100(227)
Edgemark Position:	N/A
CAD Cam Ref:	G-Lflt-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 1 LTH

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

HEALTH ▸ HYGIENE ▸ HOME

TRIDENT
Connaught House, Connaught Road,
Kingswood Business Park, Hull, HU7 3AP, England.
T: +44 (0) 1482 828100

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Sm•Art check results: G=2; O=0; R=0; - BH - 20/07/20 14:54:47

250 240 230 220 210 200 190 180 170 160 150 140 130 120 110 100 90 80 70 60 50 40 30 20 10 mm

Production line			
Manufacturing site			
Pack Tech approver	1st	2nd	
Date			
Check Criteria	Details & Comments	Checks 1st	2nd
Approvals			
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			

Version 004 07/01/2020

RB Artwork and Print Specification

Trident Reference No:	RB430610
ZEN Ref:	**TR1936640**
Action:	**D**
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Category:	Adult
Segment Group:	Double Action Tablets
Segment:	Peppermint
Pack Size:	4x6x24Tablets
Market/Country:	South Africa
Date:	20/07/20
RBH Contact:	Shivesh Patel

Artwork Type: BW Commercial

Component Code (2D if applicable):	**3158556**
2nd Component Code (if applicable):	**N/A**
Parent Technical Packaging Specification:	D0064065
Finished Goods Code:	**8065348 8063678**
Supply Point:	RB Hull
3rd Party Code	N/A
Pharmacode No/NE:	1100100(227)
Edgemark Position:	N/A
CAD Cam Ref:	G-Lflt-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	1
	LTH

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

HEALTH ▸ HYGIENE ▸ HOME

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T: +44 (0) 1482 828100

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Sm•Art check results:	G=2; O=0; R=0; - BH - 20/07/20 14:54:47	

mm 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 250