

**GAVISCON- aluminum hydroxide and magnesium carbonate liquid**  
**GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

***Active ingredient (in each 15mL tablespoonful) Regular Strength***

Aluminum hydroxide 95mg

Magnesium carbonate 358mg

***Active ingredient (in each 5mL teaspoonful) Extra Strength***

Aluminum hydroxide 254mg

Magnesium carbonate 237.5mg

***Purpose***

Antacid

***Uses***

relieves

- heartburn
- acid indigestion
- sour stomach
- upset stomach associated with these symptoms

***Warnings***

**Do not use if you have kidney disease**

**Ask a doctor or pharmacist before use if you are**

- ☐ have kidney disease.
- ☐ are on a sodium-restricted diet or a magnesium-restricted diet.
- ☐ are taking a prescription drug. Antacids may interact with certain prescription drugs.

**When using this product (Regular Strength)**

- do not take more than 8 tablespoonfuls in 24 hours
- do not use the maximum dosage for more than 2 weeks
- laxative effect may occur

**When using this product (Extra Strength)**

- do not take more than 16 teaspoonfuls in 24 hours

- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor
- laxative effect may occur

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

***Directions (Regular Strength)***

- shake well
- take 1-2 tablespoonfuls four times a day or as directed by a doctor
- take after meals and at bedtime
- dispense product only by spoon or other measuring device

***Directions (Extra Strength)***

- shake well
- take 2-4 teaspoonfuls four times a day or as directed by a doctor
- take after meals and at bedtime
- dispense product only by spoon or other measuring device

***Other information (Regular Strength)***

- **each tablespoon (15mL) contains:** magnesium 115mg, sodium 52mg
- store at up to 25°C (77°F); avoid freezing
- keep tightly closed

***Other information (Extra Strength)***

- **each teaspoon (5mL) contains:** magnesium 80mg, sodium 14mg
- store at up to 25°C (77°F); avoid freezing
- keep tightly closed

***Inactive ingredients (Regular Strength)***

benzyl alcohol, D&C yellow #10, edetate disodium, FD&C blue #1, flavor, glycerin, saccharin sodium, sodium alginate, sorbitol solution, water, xanthan gum

***Inactive ingredients (Extra Strength Cool Mint)***

benzyl alcohol, edetate disodium, flavor, glycerin, saccharin sodium, simethicone emulsion, sodium alginate, sorbitol solution, water, xanthan gum

***Inactive Ingredients (Extra Strength Cherry)***

Benzyl alcohol, edentate disodium, flavor, glycerin, saccharin sodium, simethicone emulsion, sodium alginate, sorbitol solution, water, xanthan gum

**Questions or comments?**

call toll-free (English/Spanish) **1-888-367-6471** weekdays

Distributed by:

**GlaxoSmithKline** Consumer Healthcare, L.P.

Moon Twp, PA 15108, Made in the U.S.A

**IMPORTANT:**

Do not use if foil inner seal imprinted "SEALED FOR YOUR PROTECTION" is disturbed or missing.

**Principal Display Panel**

**NDC 0135-0094-41**

**Gaviscon®**

**REGULAR STRENGTH**

**LIQUID ANTACID**

- *Fast-Acting Heartburn Relief*
- *Helps Keep Acid Down for Hours*

**COOL MINT**

**FLAVOR**

*12 fl oz (355 ml)*

©2010 GlaxoSmithKline

FRONT: 100631XB

BACK: 100632XA



**Principal Display Panel**

**NDC 0135-0095-41**

**Gaviscon®**

**EXTRA STRENGTH**

**LIQUID ANTACID**

- *Fast-Acting Heartburn Relief*
- *Helps Keep Acid Down for Hours*

**COOL MINT**

**FLAVOR**

**12 fl oz (355 ml)**

©2010 GlaxoSmithKline

FRONT: 100651XB

BACK: 100652XA



**Principal Display Panel**

NDC 0135-0574-01

**Gaviscon®**

**EXTRA STRENGTH**

**LIQUID ANTACID**

- *Fast-Acting Heartburn Relief*
- *Helps Keep Acid Down for Hours*

**CHERRY**

**FLAVOR**

*12 fl oz (355 ml)*

©2014 GlaxoSmithKline

FRONT: 103698XA

BACK: 103699XA

**NEW**

# GAVISCON<sup>®</sup>

## EXTRA STRENGTH LIQUID ANTACID

- ▼ *Fast-Acting Heartburn Relief*
- ▼ *Helps Keep Acid Down for Hours*

**CHERRY FLAVOR**

**12 fl oz (355 ml)**      **103698XA**

## GAVISCON

aluminum hydroxide and magnesium carbonate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0094
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	95 mg in 15 mL
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	358 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	

<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	GREEN	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (cool mint)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0094-41	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2011	
2	NDC:0135-0094-42	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2011	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	01/14/2011	

**GAVISCON**

aluminum hydroxide and magnesium carbonate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0095
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ALUMINUM HYDRO XIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	254 mg in 5 mL
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	237.5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
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BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT (cool mint)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0095-41	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	01/14/2011	

## GAVISCON

aluminum hydroxide and magnesium carbonate liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0574
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	254 mg in 5 mL
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ50PE7D)	MAGNESIUM CARBONATE	237.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0574-01	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2014	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	08/01/2014	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)