

**GAVISCON EXTRA STRENGTH- aluminum hydroxide and magnesium carbonate tablet, chewable**

**GAVISCON REGULAR STRENGTH- aluminum hydroxide and magnesium trisilicate tablet, chewable**

**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 ingredients (in each tablet) (Extra Strength)**

Aluminum hydroxide 160mg

Magnesium carbonate 105mg

#### **Active ingredients (in each tablet) (Regular Strength)**

Dried aluminum hydroxide gel 80mg

Magnesium trisilicate 14.2mg

### **Purpose**

Antacid

Antacid

### **Uses (Extra Strength)**

*relieves*

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

### **Uses (Regular Strength)**

temporarily relieves symptoms of:

- heartburn and acid indigestion due to acid reflux

### **Warnings (Extra Strength)**

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

- taking a prescription drug. Antacids may interact with certain prescription drugs.
- if you are on a sodium-restricted diet

### **When using this product**

- do not take more than 16 tablets in 24 hours
- do not use the maximum dosage for more than 2 weeks

### **Keep out of reach of children.**

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

### ***Warnings (Regular Strength)***

#### **Do not use**

- for peptic ulcers
- if you have trouble swallowing

#### **Ask a doctor before use if you have**

- kidney disease
- a sodium restricted diet

#### **Ask a doctor or pharmacist if you**

- are taking a prescription drug. Antacids may interact with certain prescription drugs.

#### **Stop use and ask a doctor if**

- heartburn or stomach pain continues
- you need to take this product for more than 14 days

### **Keep out of reach of children.**

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

### ***Directions (Extra Strength)***

- chew 2-4 tablets four times a day or as directed by a doctor
- take after meals and at bedtime or as needed
- for best results follow by a half glass of water or other liquid
- DO NOT SWALLOW WHOLE

### ***Directions (Regular Strength)***

- **do not swallow tablets whole**
- chew 2 to 4 tablets after meals and at bedtime as needed (up to 4 times a day) or

as directed by a doctor. For best results, drink a half glass of water or other liquid after each dose.

- do not take more than 16 tablets in 24 hours

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

- **Each tablet contains:** magnesium 35mg, sodium 20mg
- Store at up to 25°C (77°F) in a dry place

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

- **Each tablet contains:** magnesium 5mg, sodium 21 mg
- Store at up to 25°C (77°F) in a dry place

### ***Inactive ingredients (Extra Strength)***

alginic acid, calcium stearate, flavor, sodium bicarbonate, and sucrose. May contain stearic acid. Contains sorbitol or mannitol. May contain starch.

### ***Inactive ingredients (Extra Strength Cherry)***

acesulfame k, alginic acid, artificial flavor, calcium stearate, corn starch, corn syrup solids, mannitol, sodium bicarbonate, stearic acid, sucrose

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

alginic acid, calcium stearate, flavor, sodium bicarbonate, starch (may contain corn starch) and sucrose

### ***Questions or comments?***

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

### **Principal Display Panel**

**NDC 0135-0098-26**

**Gaviscon®**

**EXTRA STRENGTH**

*ANTACID*

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

**ORIGINAL FLAVOR**

**100 Chewable Tablets**

IMPORTANT: Do not use if foil inner seal printed "SEALED for YOUR PROTECTION" is disturbed or missing.

GAVISCON® is a registered trademark of the Sanofi group of companies and licensed by the GlaxoSmithKline group of companies and TORSO device is a registered trademark of the GlaxoSmithKline group of companies.

Distributed by:

**GlaxoSmithKline**

Consumer Healthcare, L.P.

Moon Twp, PA 15108

Made in France

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102597XA

The image shows the front of a Gaviscon Extra Strength Antacid box. The background is dark blue. At the top, the brand name "Gaviscon" is written in a large, white, italicized sans-serif font with a red triangle above the 'i'. Below it, a red horizontal bar contains the words "EXTRA STRENGTH" in white, bold, italicized sans-serif font, and "ANTACID" in a smaller white, italicized sans-serif font below it. On the left side, there are two bullet points with white text: "Fast-Acting Heartburn Relief" and "Helps Keep Acid Down for Hours". At the bottom left, the words "ORIGINAL FLAVOR" are written in white, italicized sans-serif font, and "100 Chewable Tablets" is written in a larger white, italicized sans-serif font below it. On the right side, there is a blue silhouette of a human torso with a red vertical line running down the center of the chest, representing the stomach area. A small registered trademark symbol (®) is visible in the bottom right corner of the graphic area.

## **Principal Display Panel**

**NDC 0135-0430-03**

**Gaviscon®**

**EXTRA STRENGTH**

ANTACID

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

**CHERRY FLAVOR**

**100 Chewable Tablets**

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# GAVISCON<sup>®</sup>

## EXTRA STRENGTH ANTACID

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



**CHERRY  
FLAVOR**

**100 Chewable Tablets**



### Principal Display Panel

NDC 0135-0096-26

**Gaviscon<sup>®</sup>**

**REGULAR STRENGTH**

*Alumina & Magnesium Trisilicate Tablets/ANTACID*

- *Relieves Heartburn Caused by Acid Reflux*
- *Unique Antacid Barrier*

**ORIGINAL FLAVOR**

**100 Chewable Tablets**

IMPORTANT: Do not use if foil inner seal printed "SEALED for YOUR PROTECTION" is disturbed or missing.

GAVISCON<sup>®</sup> is a registered trademark of the Sanofi group of companies and licensed by the GlaxoSmithKline group of companies and TORSO device is a registered trademark

of the GlaxoSmithKline group of companies.

Distributed by:

**GlaxoSmithKline**

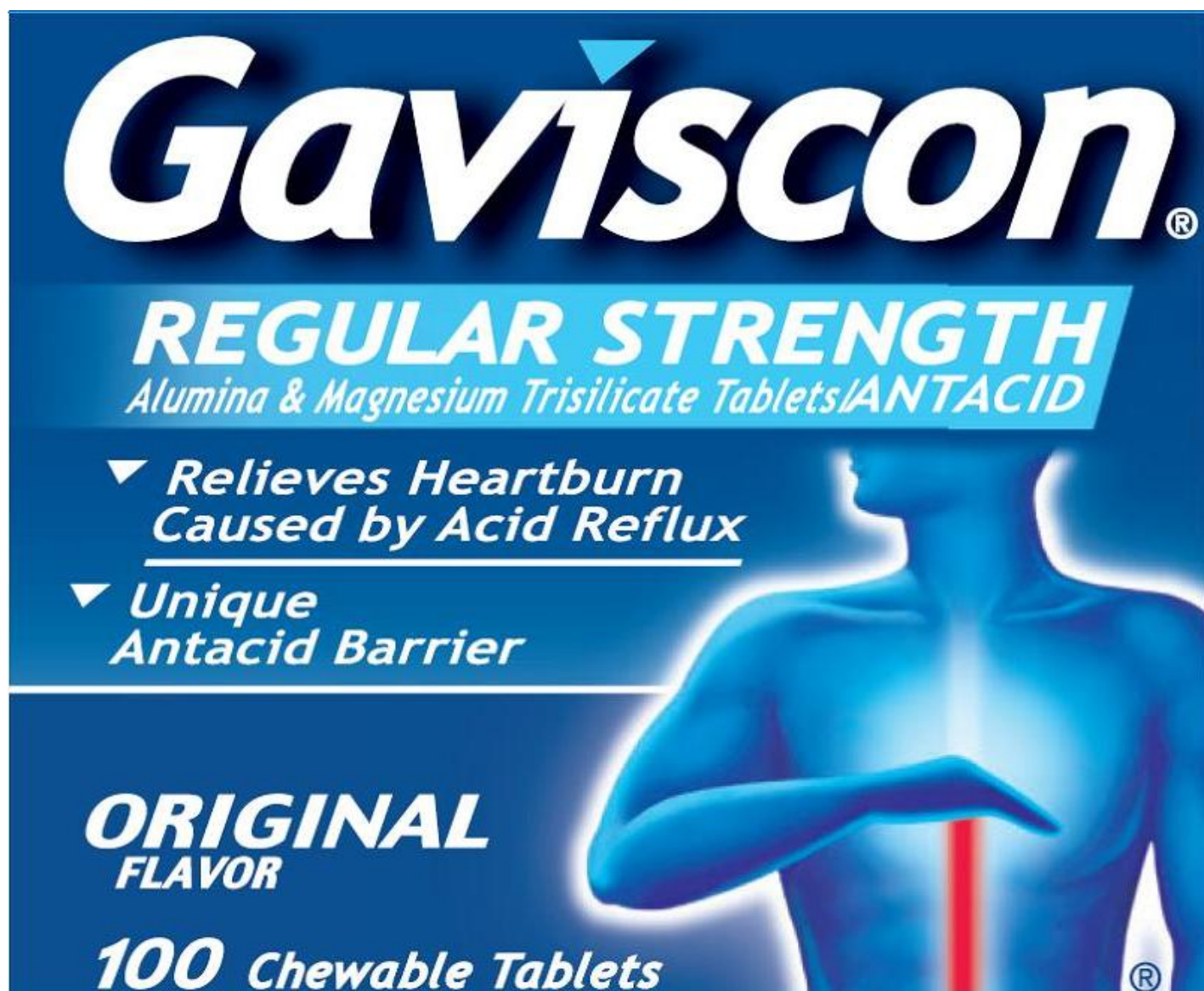
Consumer Healthcare, L.P.

Moon Twp, PA 15108

Made in France

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102598XA

The image shows the packaging for Gaviscon Regular Strength. The background is dark blue. At the top, the brand name 'Gaviscon' is written in a large, white, italicized sans-serif font with a registered trademark symbol. Below it, the words 'REGULAR STRENGTH' are in a white, bold, sans-serif font on a light blue horizontal band. Underneath that, 'Alumina & Magnesium Trisilicate Tablets/ANTACID' is written in a smaller, white, italicized font. Two bullet points with white downward-pointing triangles are listed: 'Relieves Heartburn Caused by Acid Reflux' and 'Unique Antacid Barrier'. The text 'ORIGINAL FLAVOR' is in a white, bold, italicized font. At the bottom left, '100 Chewable Tablets' is written in a white, bold, italicized font. On the right side, there is a blue silhouette of a human torso with a red vertical line indicating the esophagus. A registered trademark symbol is also present at the bottom right of the silhouette.

**Gaviscon**®

**REGULAR STRENGTH**

*Alumina & Magnesium Trisilicate Tablets/ANTACID*

▼ *Relieves Heartburn  
Caused by Acid Reflux*

▼ *Unique  
Antacid Barrier*

**ORIGINAL  
FLAVOR**

**100 Chewable Tablets**

**GAVISCON EXTRA STRENGTH**

aluminum hydroxide and magnesium carbonate tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0098
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	160 mg
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	105 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ALGINIC ACID</b> (UNII: 8C3Z4148WZ)	
<b>CALCIUM STEARATE</b> (UNII: 776XM7047L)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	VANILLA (Vanilla Mint)	<b>Imprint Code</b>	GAVICON
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0098-26	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/13/2011	

## GAVICON EXTRA STRENGTH

aluminum hydroxide and magnesium carbonate tablet, chewable

### Product Information



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0430
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	160 mg
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	105 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ALGINIC ACID</b> (UNII: 8C3Z4148WZ)	
<b>CALCIUM STEARATE</b> (UNII: 776XM7047L)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CORN SYRUP</b> (UNII: 9G5L16BK6N)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	GAVISCON
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0430-03	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/13/2011	

## GAVISCON REGULAR STRENGTH

aluminum hydroxide and magnesium trisilicate tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0096
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	80 mg
<b>MAGNESIUM TRISILICATE</b> (UNII: C2E1CI501T) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM TRISILICATE	14.2 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALGINIC ACID</b> (UNII: 8C3Z4148WZ)	
<b>CALCIUM STEARATE</b> (UNII: 776XM7047L)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCROSE</b> (UNII: C151H8M554)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	VANILLA (Vanilla Mint)	<b>Imprint Code</b>	GAVICON
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0135-0096-26	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2011	05/31/2021

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA018685	06/13/2011	05/31/2021

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