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.

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.

Distributed by:

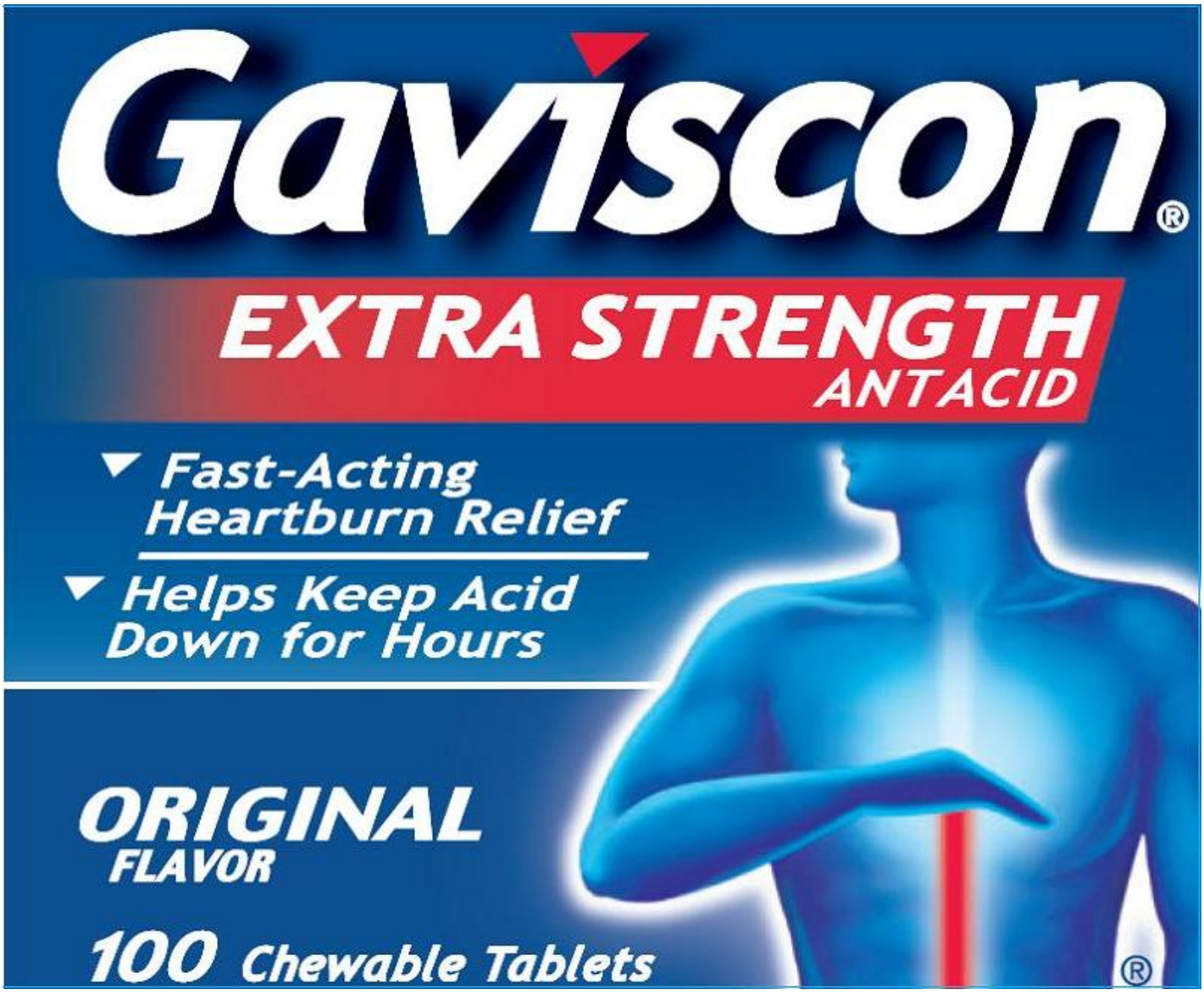
GlaxoSmithKline

Consumer Healthcare, L.P.

Moon Twp, PA 15108

Made in France

102597XA



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

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:

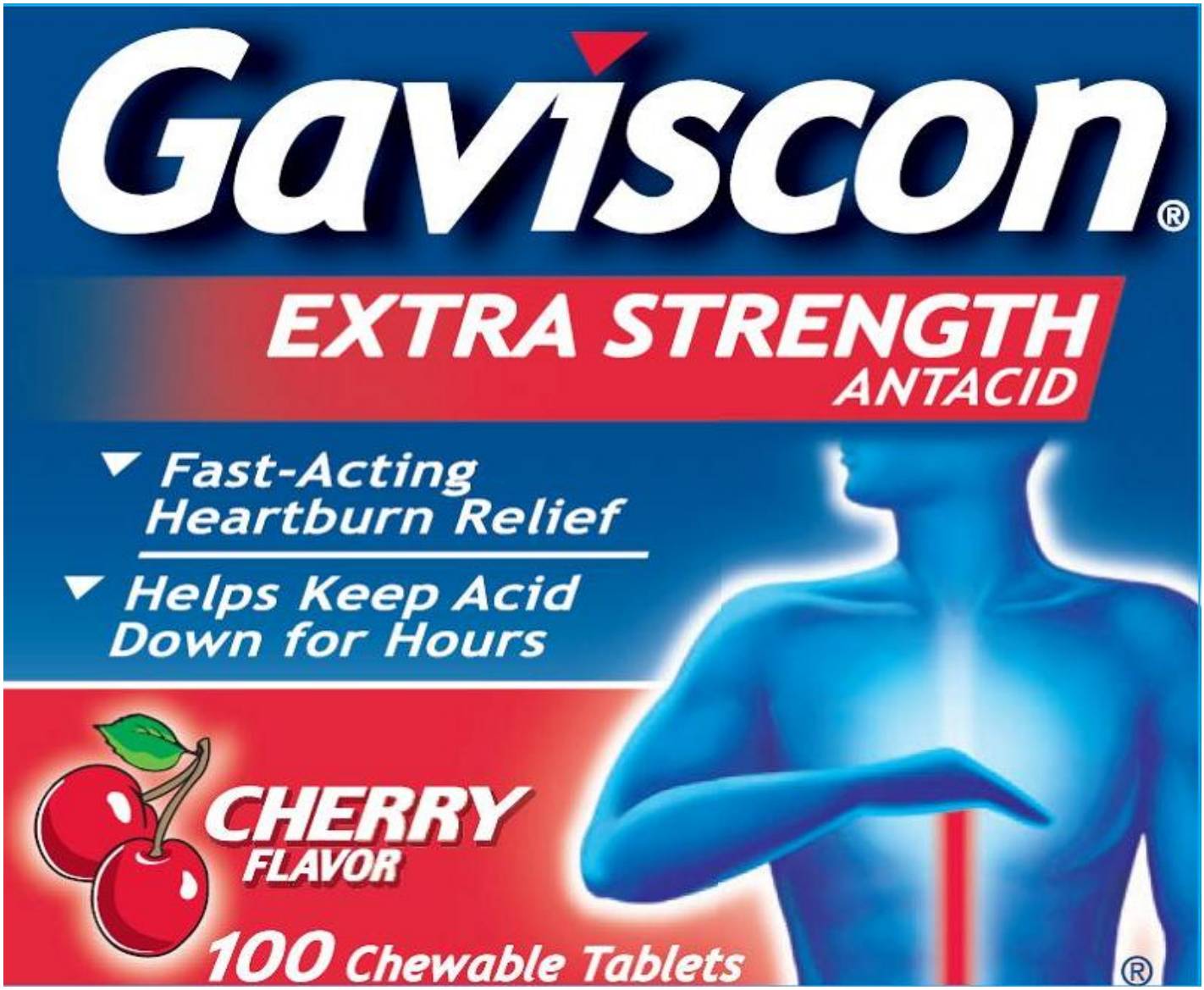
GlaxoSmithKline

Consumer Healthcare, L.P.

Moon Twp, PA 15108

Made in France

102599XA



Principal Display Panel

NDC 0135-0096-26

***Gaviscon*®**

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® 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:

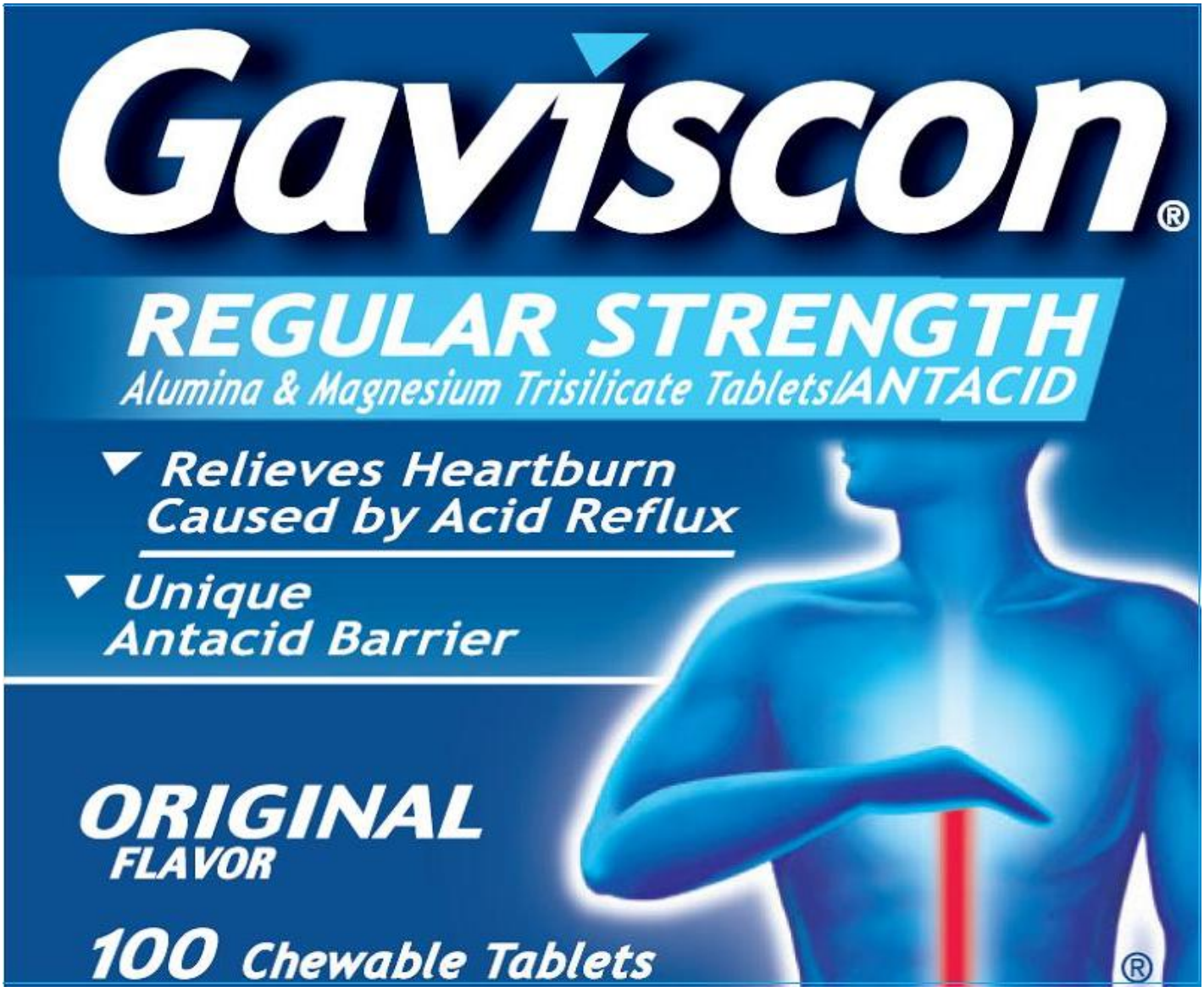
GlaxoSmithKline

Consumer Healthcare, L.P.

Moon Twp, PA 15108

Made in France

102598XA



GAVISCON EXTRA STRENGTH

aluminum hydroxide and magnesium carbonate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0098
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor	VANILLA (Vanilla Mint)	**Imprint Code**	GAVISCON
Contains			

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	

GAVISCON EXTRA STRENGTH

aluminum hydroxide and magnesium carbonate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0430
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor	CHERRY	**Imprint Code**	GAVISCON
Contains			

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

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0096
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor	VANILLA (Vanilla Mint)	**Imprint Code**	GAVISCON
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0096-26	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
NDA	NDA018685	06/13/2011	

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

Establishment

Name	Address	ID/FEI	Business Operations
TOMITA PHARMACEUTICAL CO., LTD.		690643499	API MANUFACTURE(0135-0098, 0135-0430, 0135-0096)