REGULAR STRENGTH ANTACID AND ANTIGAS- aluminum hydroxide, magnesium hydroxide, dimethicone suspension STRATEGIC SOURCING SERVICES LLC

FOS ANT ORG 629

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200 mg (equivalent to dried gel, USP) Magnesium hydroxide 200 mg Simethicone 20mg

Purposes

Antacid Antigas

Uses

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are presently taking a prescription drug.

Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than 2 weeks **If pregnant or breast-feeding,** ask a health professional before use.

Keep out of reach of children.

Directions

- shake well before use
- adults and children 12 years and older: take 2 to 4 teaspoonfuls between meals, at bedtime, or as directed by a doctor
- do not take more than 24 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks
- children under 12 years: ask a doctor

Other information

- each 5 mL teaspoonful contains: magnesium 85 mg, sodium 3 mg
- store at room temperature
- protect from freezing
- keep tightly closed

Inactive ingredients

benzyl alcohol, butylparaben, flavor (contains alcohol), hydroxyethylcellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

Questions or comments?

Call **833-358-6431**

package Label

NDC 70677-1063-1

COMPARE TO THE ACTIVE INGREDIENTS OF REGULAR STRENGTH MYLANTA®



REGULAR STRENGTH

Antacid & Antigas

Alumina, Magnesia, and Simethicone Oral Suspension

Alcohol: 0.15%

Relief of:

- Heartburn
- Acid Indiaestion
- Sour Stomach
- Pressure and Bloating

ORIGINAL FLAVOR

12 FL OZ (355 mL)

REV0124 275-05112-0

Drug Facts

TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON BOTTLE CAP IS MISSING OR BROKEN.

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Purpose

Aluminum hydroxide 200 mg (equivalent to dried gel, USP)Antacid Magnesium hydroxide 200 mgAntacid

Simethicone 20 mg...... Antigas

- Uses relieves heartburn sour stomach acid indigestion
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This product is not manufactured or distributed by the owner of the registered trademark MYLANTA®.

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975-05112-0 REV0223

REGULAR STRENGTH ANTACID AND ANTIGAS

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

HUMAN OTC DRUG NDC:70677-1063 **Product Type** Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

Basis of Ingredient Name Strength Strength

ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	200 mg in 5 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL SOLUTION (UNII: 8KW3E207O2)		

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677- 1063-1	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M001	06/01/2023	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Registrant - GCP Laboratories (965480861)

Establishment			
Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	pack(70677-1063), manufacture(70677-1063)

Revised: 2/2024 STRATEGIC SOURCING SERVICES LLC