

**REGULAR STRENGTH ANTACID- aluminum hydroxide, magnesium hydroxide, dimethicone suspension**

**Chain Drug Marketing Association**

*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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**qc ant org**

**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** 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?**

1-800-540-3765

**package Label**

NDC 63868-712-57



\*Compare to the Active Ingredients in Mylanta® Regular Strength

# Regular Strength Antacid

Antigas, Fast Acting

Alumina, Magnesia, and Simethicone Oral Suspension USP

Fast Soothing Relief of:  
Acid Indigestion  
Heartburn  
Sour Stomach  
Pressure & Bloating

Alcohol: 0.15%

Original Flavor

12 FL OZ (355 mL)

REV GC-0818  
231-05112-0

## Drug Facts

**TAMPER-EVIDENT:** Do not use if breakaway band on bottle cap is missing or broken.

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

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\*This product is not manufactured or distributed by the owner of the registered trademark MYLANTA®.



REV GC-0818  
931-05112-0



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www.qualitychoice.com  
Questions: 248-449-9300

## REGULAR STRENGTH ANTACID

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-712
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (ANTI-ESORBITOLINO) (ALUMINUM HYDROXIDE - UNIF-ESORBITOLINO)	ALUMINUM	200 mg

ALUMINUM HYDROXIDE (UNII: 3QB01Z10N0) (ALUMINUM HYDROXIDE - UNII:3QB01Z10N0)	HYDROXIDE	in 5 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON (citrus mint)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-712-57	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	03/01/2014	

**Labeler** - Chain Drug Marketing Association (011920774)

**Registrant** - GCP Laboratories (965480861)

### Establishment

Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(63868-712)