

**ALMACONE ANTACID ANTIGAS- aluminum hydroxide, magnesium hydroxide,
dimethicone suspension
RUGBY LABORATORIES**

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.

RUG ALMACONE

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
- 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

Keep out of reach of children.

Directions

- shake well before use
- adults and children 12 years of age 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

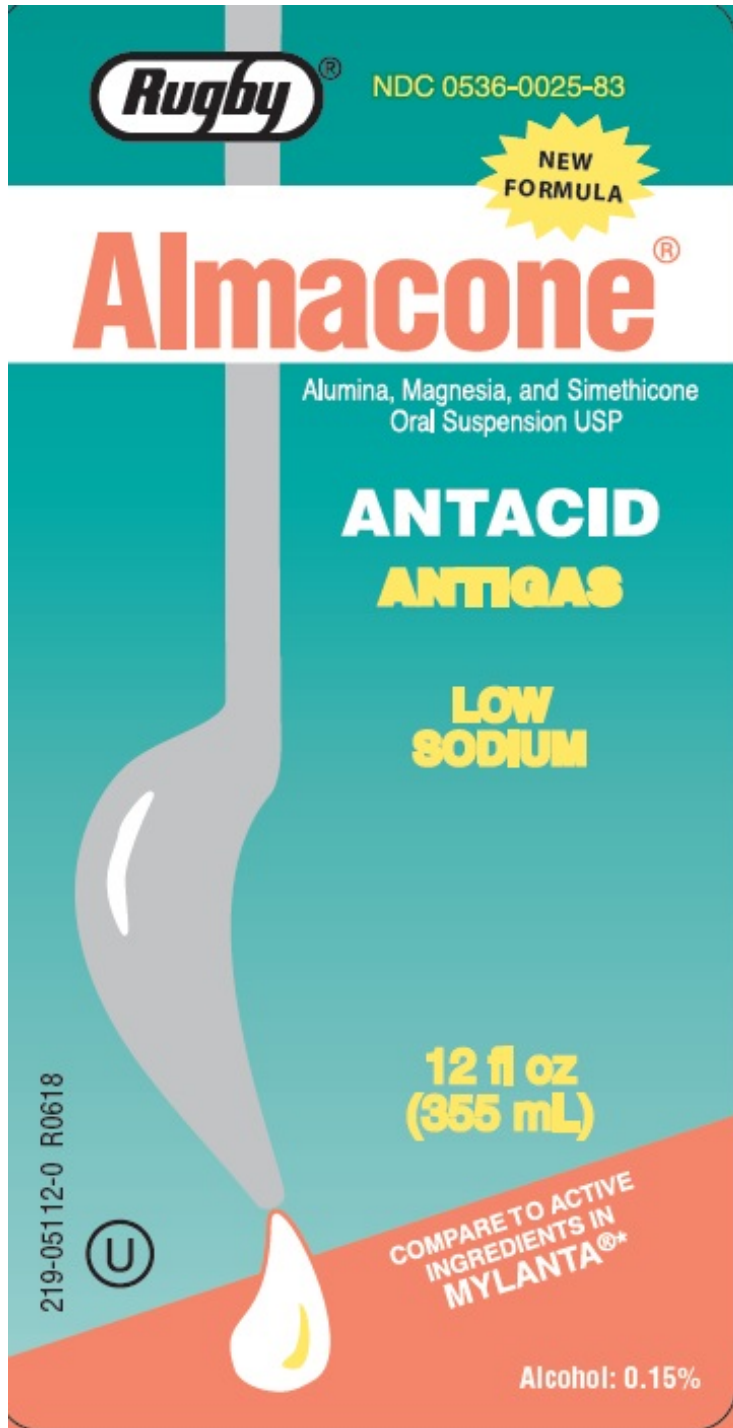
Inactive ingredients

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

Questions or comments?

1-800-645-2158

package Label



Drug Facts		TAMPER EVIDENT: Do not use if breakaway band on cap is broken or missing.
Active ingredients (in each 5 mL teaspoonful)	Purposes	
Aluminum hydroxide 200 mg (equivalent to dried gel USP)Antacid	
Magnesium hydroxide 200 mgAntacid	
Simethicone 20 mgAntigas	
Uses relieves • heartburn • sour stomach • acid indigestion • 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 Keep out of reach of children.		
Directions • shake well before use • adults and children 12 years of age 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		
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Rugby Laboratories
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
www.rugbylaboratories.com
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ALMACONE ANTACID ANTIGAS

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-0025
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (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: 3QPIU3FV8)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-0025-83	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	01/05/2011	

Labeler - RUGBY LABORATORIES (079246066)

Registrant - GCP Laboratories (965480861)

Establishment

Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(0536-0025)

Revised: 12/2018

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