

ALMACONE DOUBLE STRENGTH- 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 DS

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 400 mg (equivalent to dried gel, USP)
Magnesium hydroxide 400 mg
Simethicone 40mg

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 12 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 165 mg, sodium 5 mg
- store at room temperature
- protect from freezing
- keep tightly closed

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor (contains alcohol), hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

Questions or comments?

1-800-645-2158

package Label

Rugby® NDC 0536-0015-83

Almacone®

DOUBLE STRENGTH

Alumina, Magnesia, and Simethicone
Oral Suspension USP

ANTACID ANTIGAS

LOW
SODIUM

12 fl oz
(355 mL)

219-06122-4 R0618

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COMPARE TO ACTIVE
INGREDIENTS IN MYLANTA®
EXTRA STRENGTH*

Alcohol: 0.5%

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

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Magnesium hydroxide 400 mg.....	Antacid
Simethicone 40 mg.....	Antigas

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• Rugby Laboratories is not affiliated with the owner of the registered trademark MYLANTA®.
Distributed by:
Rugby Laboratories
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
www.rugbylaboratories.com
Re-order No. 370005
919-06122-6 Rev. 08/18 R-99

ALMACONE DOUBLE STRENGTH

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-0015
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	400 mg in 5 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	400 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	40 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPIU3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON (lemon)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-0015-83	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(0536-0015)

