

RUGBY ALMACONE- aluminum hydroxide, magnesium hydroxide, simethicone 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.

Rugby Laboratories Almacone[®] Drug Facts

Active ingredients (in each 10 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 400 mg

Magnesium hydroxide 400 mg

Simethicone 40 mg

Purposes

Antacid

Antigas

Uses

relieves

- heartburn
- acid indigestion
- sour stomach
- upset stomach due to these symptoms
- pressure and bloating commonly 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.

When using this product

do not exceed 120 mL in a 24-hour period, or use the maximum dosage for more than 2 weeks, unless directed by a doctor

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- shake well before use
- measure with dosing cup provided
- **adults and children 12 years and over:** 10 mL – 20 mL between meals, at bedtime or as directed by a doctor
- do not take more than 120 mL in any 24 hour period
- do not use the maximum dosage for more than 2 weeks
- **children under 12 years:** ask a doctor
- mL = milliliter

Other information

- **each 10 mL contains:** magnesium 175 mg
- **does not meet USP requirements for preservative effectiveness**
- store at 20-25°C (68-77°F), do not freeze

Inactive ingredients

butylparaben, flavor, hypromellose, microcrystalline cellulose and carboxymethylcellulose sodium, peppermint oil, propylparaben, purified water, simethicone emulsion, sorbitol, sorbitol solution

Questions or comments?

1-800-645-2158

Principal Display Panel

Regular Strength

Almacone®

Aluminum Hydroxide

Magnesium Hydroxide, Simethicone

ANTACID

ANTIGAS

VERY LOW SODIUM

12 fl oz (355 mL)

ALCOHOL 0.2%

Rugby[®]

NDC 0536-1185-83

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Almacone[®]

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Magnesium Hydroxide, Simethicone

ANTACID ANTIGAS

**VERY LOW
SODIUM**



**12 fl oz
(355 mL)**

R-05 REV. 04/18

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: 35740 BT F1

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|---|----------|
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Inactive ingredients butylparaben, flavor, hypromellose, microcrystalline cellulose and carboxymethylcellulose sodium, peppermint oil, propylparaben, purified water, simethicone emulsion, sorbitol, sorbitol solution

Drug Facts (continued)

Questions or
comments?
1-800-645-2158

Gluten Free

Distributed by:
Rugby Laboratories
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Livonia, MI 48152
www.rugbylaboratories.com
Re-Order No. 370622
REV. 04/18 R-05

: 35740 BT B1

DO NOT USE IF
PRINTED NECKBAND
IS BROKEN OR
MISSING



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RUGBY ALMACONE

aluminum hydroxide, magnesium hydroxide, simethicone suspension

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1185 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|-----------------|
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0) | ALUMINUM HYDROXIDE | 400 mg in 10 mL |
| MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P) | MAGNESIUM HYDROXIDE | 400 mg in 10 mL |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 40 mg in 10 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| BUTYLPARABEN (UNII: 3QP1U3FV8) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |

Product Characteristics

| | | | |
|----------|----------------|--------------|--|
| Color | WHITE (opaque) | Score | |
| Shape | | Size | |
| Flavor | MINT, LEMON | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0536-1185-83 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/19/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part331 | 12/19/2018 | |

