

ANTACID - aluminum hydroxide, magnesium hydroxide, simethicone liquid
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 Regular Strength Antacid Liquid

ACTIVE INGREDIENTS (in each 10 mL)

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

PURPOSE

Antacid
Antacid
Antigas

USE(S)

relieves:

- acid indigestion
- heartburn
- sour stomach
- upset stomach and gas associated with these symptoms

WARNINGS

Do not take more than 80 mL in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

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 DOCTOR

if symptoms last more than two weeks

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS

- **shake well before use**
- mL = milliliter
- adults and children 12 years and older: take 10 mL to 20 mL four times a day, or as directed by a doctor
- children under 12 years: consult a doctor

OTHER INFORMATION

- **each 10 mL contains:** magnesium 170 mg, sodium 5 mg
- store at controlled room temperature 20°C-25°C (68°-77°F)
- do not freeze

INACTIVE INGREDIENTS

ethyl alcohol, flavor, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol

PRINCIPAL DISPLAY PANEL

Rugby

NDC 0536-1293-83

Regular Strength Antacid Liquid

Aluminum hydroxide, 400 mg
Magnesium hydroxide, 400 mg
Simethicone, 40 mg

Antacid and Antigas Original Flavor

Relief of:


Heartburn

Acid Indigestion

Sour Stomach

Pressure & Bloating

12 FL OZ (355 mL)
 Alcohol content 0.2% v/v



NDC 0536-1293-83

Regular Strength

Antacid Liquid

Aluminum Hydroxide, 400 mg
 Magnesium Hydroxide, 400 mg
 Simethicone, 40 mg

Antacid and Antigas Original Flavor

Relief of:
 Heartburn
 Acid Indigestion
 Sour Stomach
 Pressure and Bloating

12 FL OZ (355 mL)
 Alcohol Content 0.2% v/v

Drug Facts **DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING**

| Active ingredients (in each 10 mL) | Purpose |
|--|---------|
| Aluminum hydroxide (equiv. to dried gel, USP) 400 mg | Antacid |
| Magnesium hydroxide 400 mg | Antacid |
| Simethicone 40 mg | Antigas |

Uses relieves: ■ acid indigestion ■ heartburn ■ sour stomach
 ■ upset stomach and gas associated with these symptoms

Warnings
 Do not take more than 80 mL in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.
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 two weeks
Keep out of reach of children.

Directions ■ shake well before use ■ mL = milliliter
 ■ adults and children 12 years and older: take 10 mL to 20 mL four times a day, or as directed by a doctor ■ children under 12 years: consult a doctor


Other information ■ each 10 mL contains: magnesium 170 mg, sodium 5 mg ■ store at controlled room temperature 20°C-25°C (68°F-77°F) ■ do not freeze

Inactive ingredients ethyl alcohol, flavor, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol.

Distributed by:
RUGBY® LABORATORIES
 Livonia, MI 48152

Questions or comments?
Call 1-800-645-2158
www.rugbylaboratories.com

Rev. 05/21 R-30 Re-order No. 371027 MFR# 53041



UNWARNISHED AREA FOR LOT & EXP (LINE DOES NOT PRINT)

ANTACID

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1293 |
| 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) | MAGNESIUM HYDROXIDE | 400 mg in 10 mL |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 40 mg in 10 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SORBITOL (UNII: 506T60A25R) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0536-1293-83 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/02/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part331 | 06/02/2021 | |

Labeler - Rugby Laboratories (079246066)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| Guardian Drug Company | | 119210276 | MANUFACTURE(0536-1293) |

Revised: 6/2021

Rugby Laboratories