

## **ALUMINUM HYDROXIDE- aluminum hydroxide 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.*

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### **Rugby aluminum hydroxide**

#### **Active ingredient (in each 5 mL teaspoonful)**

Aluminum hydroxide 320 mg

#### **Purpose**

Antacid

#### **Uses**

relieves

- heartburn
- acid indigestion
- sour stomach

#### **Warnings**

**Ask a doctor or pharmacist before use if you are** taking a prescription drug.

Antacids may interact with certain prescription drugs.

**When using this product** you may get constipated

**Stop use and ask a doctor if** symptoms last more than 2 weeks

**Keep out of reach of children.**

#### **Directions**

- shake well before using
- do not take more than 12 teaspoonfuls in 24 hours
- do not use the maximum dosage for more than 2 weeks
- **dosage:** 2 teaspoonfuls 5-6 times daily after meals and at bedtime followed by a sip of water if needed

#### **Other information**

- store at room temperature
- protect from freezing
- keep tightly closed
- **TAMPER-EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OR MISSING.**

#### **Inactive ingredients**

benzyl alcohol, butylparaben, flavor, glycerin, hydroxyethylcellulose, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol solution

**Questions or comments?**

**1-800-645-2158**

**package Label**

compare to the active ingredient in AMPHOJEL

**Rugby**

NDC 0536-0091-85

MINT FLAVOR

Aluminum Hydroxide Gel, USP

ANTACID

SUGAR FREE

This is a bulk package. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.

Rugby Laboratories, INC. is not affiliated with the owner of the trademark Amphojel.

16 fl oz (473 mL)

COMPARE TO  
ACTIVE INGREDIENT IN  
AMPHOJEL®\*



NDC 0536-0091-85

MINT FLAVOR

# Aluminum Hydroxide Gel, USP ANTACID

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219-01201-2

Rev. 07/17

## Drug Facts

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Distributed by:  
Rugby Laboratories  
17177 N Laurel Park Drive,  
Suite 233  
Livonia, MI 48152  
www.rugbylaboratories.com



Rev. 07/17  
R-99  
Re-order No. 370009 919-01201-3

## ALUMINUM HYDROXIDE

aluminum hydroxide liquid

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-0091 |
| Route of Administration | ORAL           |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength  | Strength       |
|--|--------------------|----------------|
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0) | ALUMINUM HYDROXIDE | 320 mg in 5 mL |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH)                            |          |
| BUTYLPARABEN (UNII: 3QP1U3FV8)                               |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                  |          |
| HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45) |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                               |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                             |          |
| WATER (UNII: 059QF0KO0R)                                     |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                          |          |
| SORBITOL (UNII: 506T60A25R)                                  |          |

## Product Characteristics

|          |             |              |  |
|----------|-------------|--------------|--|
| Color    |             | Score        |  |
| Shape    |             | Size         |  |
| Flavor   | MINT (mint) | Imprint Code |  |
| Contains |             |              |  |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0536-0091-85 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/01/2017           |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part331                                  | 02/01/2005           |                    |

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - GCP Laboratories (965480861)

## Establishment

| Name             | Address | ID/FEI    | Business Operations    |
|------------------|---------|-----------|------------------------|
| GCP Laboratories |         | 965480861 | manufacture(0536-0091) |

Revised: 11/2017

Rugby Laboratories