ANTACID- aluminum hydroxide, magnesium hydroxide, simethicone liquid Rij Pharmaceutical Corporation

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.

Drug Facts

Active ingredients (in each 5 mL = 1 teas poonful)

Aluminum hydroxide (Equi. To Dried Gel, USP) 200 mg Magnesium hydroxide 200 mg Simethicone 20 mg

Purpose

Antacid

Antigas

Uses

relieves

- heartburn
- acid indigestion
- sour stomach
- associated symptoms of gas and upset stomach
- overindulgence of food and drink

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 for more than 2 weeks

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center immediately.

Directions

shake well before each use

- Adults/children 12 years and older, take 2 4 teaspoonsful between meals, at bedtime or as directed by a physician
- do not take more than 12 teaspoonsful in 24
- do not use the maximum dosage for more than 2 weeks
- children under 12 years: consult a physician

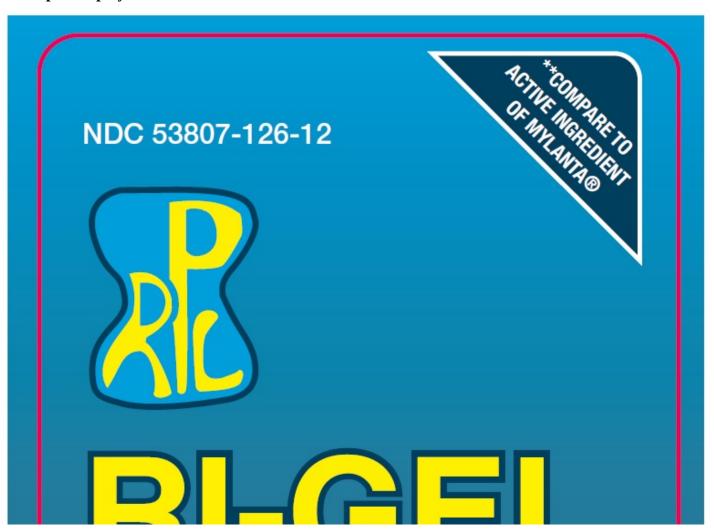
Other information

- TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING
- Store at room temperature 15° 30°C (59° 86°F)
- keep tightly closed
- protect from freezing
- each teaspoon (5 mL) contains: magnesium 83 mg
- each teaspoon (5 mL) contains: sodium 1 mg
- does not meet USP requirements for preservative effectiveness

Inactive ingredients

flavors, hypromellose, parabens, saccharin, sodium hypochlorite, sorbitol, water and xanthan gum

Principal Display Panel





ANTACID ANTI-GAS

Alumina, Magnesia and Simethicone Oral suspension

- NON-CONSTIPATING
- PLEASANT TASTING

Fast acting relief of:

- Heartburn
- Sour Stomach
- Acid Indigestion
- Gas

Original Flavor 12 Fl. Oz. (355 ml)

RI-GEL

Uses relieves ■ heartburn ■ acid indigestion ■ sour stomach ■ associated symptoms of gas and upset stomach ■ overindulgence of food and drink

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. In case of accidental overdose, get medical help or contact a Poison Control Center immediately.

Directions - shake well before each use

- Adults/children 12 years and older, take 2-4 teaspoonfuls between meals, at bedtime or as directed by a physician
- do not take more than 12 teaspoonsful in 24 hour period
- do not use the maximum dosage for more than 2 weeks
- Children under 12 years: consult a physician

Other information

- TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.
- ■store at room temperature 15°-30°C (59°-86°F)
- ■keep tightly closed protect from freezing
- ■each teaspoon (5 mL) contains: magnesium 83 mg
- ■each teaspoon (5 mL) contains: sodium 1 mg
- does not meet USP requirements for preservative effectiveness

Inactive ingredients: flavors, hypromellose, parabens, saccharin, sodium hypochlorite, sorbitol, water and xanthan gum.

**This product is not manufactured or distributed by the owner of the registered trademark Mylanta®.

RIJ PHARMACEUTICAL CORP. 40 Commercial Avenue Middletown, NY 10941 REV 01/13 53807-12612 2

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ANTACID

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-126
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 HYDRO XIDE	200 mg in 5 mL	
MAGNESIUM HYDRO XIDE (UNII: NBZ3Q Y004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
BUTYLPARABEN (UNII: 3QPI1U3FV8)			
SACCHARIN (UNII: FST467XS7D)			
SODIUM HYPO CHLO RITE (UNII: DY38 VHM5OD)			
SORBITOL (UNII: 506T60A25R)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
XANTHAN GUM (UNII: TTV12P4NEE)			
LEMON OIL (UNII: 19 GRO 824LL)			

Product Characteristics			
Color	WHITE (opaque)	Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

1	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-126-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-126-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rij Pharmaceutical Corporation		144679156	manufacture(53807-126)	

Revised: 4/2018 Rij Pharmaceutical Corporation