RIGINIC ANTACID LIQUID- aluminum hydroxide and magnesium carbonate 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 ingredient (in each 15mL tables poonful)

Aluminum Hydroxide 95mg

Magnesium Carbonate, Anhydrous 358mg

Purpose

Antacid

Uses

relieves

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

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet
- a sodium-restricted diet

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,

• it may have a laxative effect

Stop use and ask a doctor if

symptoms last more than two weeks

Keep out of reach of children.

Directions

- shake well before using
- do not take more than 8 tablespoons in 24 hours
- do not use the maximum dosage for more than 2 weeks
- dosage: 1-2 tablespoons after meals and at bedtime followed by milk or water

Other information

- TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING
- each tablespoon contains: sodium 19 mg, magnesium 124 mg, calcium 3 mg
- Store at room temperature 15° 25°C (59° 77°F)
- keep tightly closed
- avoid freezing

Inactive ingredients

colors, edetate disodium, flavors, glycerin, methylparaben, propylparaben, saccharin, sodium alginate, sodium hypochlorite, sorbitol solution, water, xanthan gum

Principal Display Panel



NDC# 53807-137-12

Riginic Antacid Liquid

REGULAR STRENGTH LIQUID ANTACID

Fast- Acting *Heartburn* Relief

For the relief of Acid Indigestion



MINT FLAVOR

Compare to the active ingredients of Gaviscon®*

Shake Well Before Using Read back label before using

12 fl oz (355mL)

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

RIJ PHARMACEUTICAL CORP. 40 Commercial Avenue Middletown, NY 10941



RIGINIC ANTACID LIQUID

aluminum hydroxide and magnesium carbonate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-137
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE UNII:5QB0T2IUN0) MAGNESIUM CARBO NATE (UNII: 0E53J927NA) (CARBO NATE ION UNII:7UJQ5OPE7D) MAGNESIUM CARBO NATE in 15 mL

Inactive Ingredients		
Ingredient Name	Strength	
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A218 C7H19T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
SACCHARIN (UNII: FST467XS7D)		
SO DIUM ALGINATE (UNII: C269C4G2ZQ)		
SO DIUM HYPO CHLO RITE (UNII: DY38 VHM5OD)		
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor	MINT (cool mint)	Imprint Code	
Contains			

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:53807-137-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	04/03/2013	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rij Pharmaceutical Corporation		144679156	manufacture(53807-137)	