ANTACID DOUBLE STRENGTH- 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) (One teaspoonful)

Aluminum Hydroxide (Equi. to Dried Gel, USP) 400 mg Magnesium Hydroxide 400 mg Simethicone 40 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 and children 12 years, take 2 4 teaspoonsful 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: ask a doctor

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 165 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, xanthan gum and water

Principal Display Panel

NDC 53807-158-12 Compare to the active ingredient in Extra Strength Mylanta®†



EXTRA STRENGTH

ANTAGD

ANTACID • ANTI-GAS

Magnesia & Alumina
Oral Suspension
with Simethicone

- Non-Constipating
- Pleasant Tasting





12 FL. OZ. (355 mL)

EXTRA STRENGTH ANTACID

Drug Facts

Active Ingredients

(In each 5 ml) (One teaspoonful)

Purpose

Aluminum Hydroxide

(Equi. to Dried Gel, USP) 400 mgAntacid Magnesium Hydroxide 400 mgAntacid Simethicone 40 mgAntacid

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

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

†This product is not manufactured or distributed by Johnson & Johnson • Merck, owner of the registered trademark MYLANTA® Maximum Strength.

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

Rev.06/12

Manufactured By: RIJ PHARMACEUTICAL CORP. 40 Commercial Avenue Middletown, NY 10941

Distributed By: Kinray Inc., Whitestone, NY 11357 3 53807-158-12 3

ANTACID DOUBLE STRENGTH

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-158
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	400 mg in 5 mL	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	400 mg in 5 mL	
DIMETHICO NE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	40 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 8 2 4 L L)			

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

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:53807-158-05	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
	2 NDC:53807-158-12	355 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(53807-158)	

Revised: 4/2018 Rij Pharmaceutical Corporation