

**ALUMINUM HYDROXIDE, MAGNESIUM HYDROXIDE AND SIMETHICONE-  
aluminum hydroxide, magnesium hydroxide, and simethicone suspension  
Rising Pharma Holdings, Inc.**

*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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**Aluminum Hydroxide, Magnesium Hydroxide and Simethicone 1,200-1,200-120 mg/30 mL, 2,400-2,400-240 mg/30 mL**

**Drug Facts**

**1,200-1,200-120 mg/30 mL**

**Active ingredient per 30mL (1 Unit Dose)**

Aluminum hydroxide 1,200mg (equivalent to dried gel USP)  
Magnesium hydroxide 1,200mg  
Simethicone 120mg

**2,400-2,400-240 mg/30 mL**

**Active ingredient per 30mL (1 Unit Dose)**

Aluminum hydroxide 2,400mg (equivalent to dried gel USP)  
Magnesium hydroxide 2,400mg  
Simethicone 240mg

**Purpose**

Antacid

Antigas

**Uses**

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

**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

**If pregnant or breast-feeding,** ask a healthcare professional before use

**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

**Directions • shake well before use**

### **1,200-1,200-120 mg/30 mL**

- Do not use more than 4 unit dose (120 mL) in a 24 hour period or use the maximum dose for more than 2 weeks

<b>age</b>	<b>dose</b>
Adults and children over 12 years of age	Take 30 mL, one unit dose, between meals and at bedtime, or as directed by a doctor. Do not exceed 4 x 30 mL unit dose (120 mL) in a 24 hour period
Children under 12 years of age	Ask a doctor

### **2,400-2,400-240 mg/30 mL**

- Do not use more than 2 unit dose (60 mL) in a 24 hour period or use the maximum dose for more than 2 weeks

<b>age</b>	<b>dose</b>
Adults and children over 12 years of age	Take 30 mL, one unit dose, one to two times daily or as directed by a doctor. Do not exceed 2 x 30 mL unit dose (60 mL) in a 24 hour period
Children under 12 years of age	Ask a doctor

### **Other information**

#### **1,200-1,200-120 mg/30 mL**

- **each 30 mL (unit dose) contains** magnesium 510 mg and sodium 18 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- protect from freezing
- do not use if lid is torn or broke

#### **2,400-2,400-240 mg/30 mL**

- **each 30 mL (unit dose) contains** magnesium 990 mg and sodium 6 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- protect from freezing
- do not use if lid is torn or broken

#### **1,200-1,200-120 mg/30 mL / 2,400-2,400-240 mg/30 mL**

**Inactive ingredients** benzyl alcohol, butylparaben, carboxy-methylcellulose sodium, flavor, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

### **NDC Information -**

#### **1,200-1,200-120 mg/30 mL**

**Each 30 mL** of Aluminium Hydroxide / Magnesium Hydroxide / Simethicone contains Aluminum hydroxide 1,200 mg, Magnesium hydroxide 1,200 mg and Simethicone 120 mg and is supplied in the following oral dosage forms:

**NDC 57237-316-03 unit dose cup 30 mL**

**NDC 57237-316-31 (100 x 30 mL) unit-dose cups**

2,400-2,400-240 mg/30 mL


Each 30 mL of Aluminum Hydroxide / Magnesium Hydroxide / Simethicone contains Aluminum hydroxide 2,400 mg, Magnesium hydroxide 2,400 mg and Simethicone 240 mg and is supplied in the following oral dosage forms:

NDC 57237-324-03 unit dose cup 30 mL  
NDC 57237-324-31 (100 x 30 mL) unit-dose cups

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

1,200-1,200-120 mg/30 mL

Case Label NDC 57237-316-31



NDC 57237-316-31

**Aluminum Hydroxide,  
Magnesium Hydroxide  
and Simethicone**

Antacid &  
Antigas

1,200-1,200-120 mg/30 mL

- Sugar Free

**USUAL DOSAGE:** See attached Drug Facts

FOR INSTITUTIONAL USE ONLY

100 x 30 mL Unit-Dose Cups

**Drug Facts**

**Active ingredient per 30mL (1 Unit Dose)**  
Aluminum hydroxide 1,200mg .....Antacid  
(equivalent to dried gel USP)  
Magnesium hydroxide 1,200mg .....Antacid  
Simethicone 120mg .....Antigas

**Purpose**  
Antacid  
Antigas

**Uses** relieves • heartburn • sour stomach • acid indigestion • the symptoms related to gas

**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**  
**If pregnant or breast-feeding, ask a healthcare professional before use**  
**Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).**

**Directions** • shake well before use  
• Do not use more than 4 unit dose (120mL) in a 24 hour period or use the maximum dose for more than 2 weeks


age	dose
Adults and children over 12 years of age	Take 30mL, one unit dose, between meals and at bedtime, or as directed by a doctor. Do not exceed 4 x 30 mL unit dose (120mL) in a 24 hour period
Children under 12 years of age	Ask a doctor

**Other information**  
• each 30mL (unit dose) contains magnesium 510 mg and sodium 18 mg  
• store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]  
• protect from freezing  
• do not use if lid is torn or broke

**Inactive ingredients** benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution


**Questions or comments?** Call 1-844-474-7464

**Distributed by:**  
Rising Pharma Holdings, Inc.  
East Brunswick, NJ 08816  
FG-30/Iss.: 04/2023

  
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NDC 57237-316-31

  
 N 57237 31631 3

**Aluminum Hydroxide,  
Magnesium Hydroxide and Simethicone**

**1,200-1,200-120 mg/30 mL**

100 x 30 mL Unit-Dose Cups



LOT# \_\_\_\_\_  
Exp. Date: \_\_\_\_\_

Unvarnished Area

1,200-1,200-120 mg/30 mL

Lid Label NDC 57237-316-03

Delivers 30 mL

# Aluminum Hydroxide / Magnesium Hydroxide / Simethicone ANTACID & ANTIGAS

1,200-1,200-120 mg/30 mL

Shake Well | For Institutional Use Only | See Label

Dist. By: Rising Pharma Holdings, Inc., NJ, 08816 Iss. 06/2023 FG-30



5723731603


Exp. yyyy/mm Lot# XXXXXX



1

2,400-2,400-240 mg/30 mL

Case Label NDC 57237-324-31



NDC 57237-324-31

**Aluminum Hydroxide,  
Magnesium Hydroxide  
and Simethicone**

**Antacid &  
Antigas**

2,400-2,400-240 mg/30 mL

- Sugar Free

**USUAL DOSAGE:** See attached Drug Facts

FOR INSTITUTIONAL USE ONLY

100 x 30 mL Unit-Dose Cups

**Drug Facts**

**Active Ingredient per 30mL (1 Unit Dose)**

Aluminum hydroxide 2,400mg	Antacid
Magnesium hydroxide 2,400mg	Antacid
Simethicone 240mg	Antigas

**Uses** relieves • heartburn • sour stomach • acid indigestion • the symptoms referred to as gas

**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

If pregnant or breast-feeding, ask a healthcare professional before use  
Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

**Directions** • shake well before use  
• Do not use more than 2 unit doses (60mL) in a 24 hour period or use the maximum dose for more than 2 weeks

age	dose
Adults and children over 12 years of age	Take 30mL, one unit dose, one to two times daily or as directed by a doctor. Do not exceed 2 x 30 mL unit dose (60mL) in a 24-hour period
Children under 12 years of age	Ask a doctor


**Other Information**

- each 30mL (unit dose) contains magnesium 990 mg and sodium 6 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- protect from freezing
- do not use if lid is torn or broken


**Inactive Ingredients:** benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution.

**Questions or comments?** Call 1-844-474-7464

Distributed by:  
Rising Pharma Holdings, Inc.  
East Brunswick, NJ 08816  
FG-44/Iss. 07/2023

  
 N 57237 32431 8


NDC 57237-324-31

  
 N 57237 32431 8

**Aluminum Hydroxide,  
Magnesium Hydroxide and Simethicone**

2,400-2,400-240 mg/30 mL

100 x 30 mL Unit-Dose Cups

  
 LOT#  
 Exp. Date: Unvarnished Area

2,400-2,400-240 mg/30 mL  
Lid Label NDC 57237-324-03

Delivers 30 mL

# Aluminum Hydroxide / Magnesium Hydroxide / Simethicone

ANTACID & ANTIGAS

2,400-2,400-240 mg/30 mL

Shake Well | For Institutional Use Only | See Label

Dist. By: Rising Pharma Holdings, Inc., NJ, 08816 Iss. 08/2023 FG-44



5723732403

Exp. yyyy/mm Lot# XXXXXX



## ALUMINUM HYDROXIDE, MAGNESIUM HYDROXIDE AND SIMETHICONE

aluminum hydroxide, magnesium hydroxide, and simethicone suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-316
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	1200 mg in 30 mL
<b>MAGNESIUM HYDROXIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	1200 mg in 30 mL
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	120 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:57237			

1	NDC:57237-316-31	100 in 1 BOX, UNIT-DOSE	08/15/2023	
1	NDC:57237-316-03	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part331	08/15/2023		

## ALUMINUM HYDROXIDE, MAGNESIUM HYDROXIDE AND SIMETHICONE

aluminum hydroxide, magnesium hydroxide, and simethicone suspension

<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57237-324	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)		ALUMINUM HYDROXIDE	2400 mg in 30 mL	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)		MAGNESIUM HYDROXIDE	2400 mg in 30 mL	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	240 mg in 30 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
PROPYLPARABEN (UNII: Z8IX25C1OH)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:57237-324-31	100 in 1 BOX, UNIT-DOSE	07/05/2023	
1	NDC:57237-324-03	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	07/05/2023	

**Labeler** - Rising Pharma Holdings, Inc. (116880195)

Revised: 8/2023

Rising Pharma Holdings, Inc.