

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

**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

age	dose
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

age	dose
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 Aluminium 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 (equivalent to dried gel USP)
 Magnesium hydroxide 1,200mg
 Simethicone 120mg

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/lss.: 04/2023



NDC 57237-316-31




N 3 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



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

Case Label 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 related 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 dose (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 980 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, carbonylmethylcellulose, 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 3 57237 32431 8

NDC 57237-324-31




N 3 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# Unvarnished Area

Exp. Date:

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



Exp. yyyy/mm Lot# XXXXXX



5723732403

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
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	1200 mg in 30 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	1200 mg in 30 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	120 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (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
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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M001.15	08/15/2023	

ALUMINUM HYDROXIDE, MAGNESIUM HYDROXIDE AND SIMETHICONE

aluminum hydroxide, magnesium hydroxide, and simethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-324
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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	
Inactive Ingredients				
Ingredient Name		Strength		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0K00R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL SOLUTION (UNII: 8KWBE207O2)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 Drug	M001.15	07/05/2023		

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 10/2024

Rising Pharma Holdings, Inc.