

ALUMINA, MAGNESIA, AND SIMETHICONE ORAL SUSPENSION REGULAR STRENGTH- alumina, magnesia, and simethicone oral suspension regular strength suspension VistaPharm, 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.

Alumina, Magnesia, and Simethicone Oral Suspension Regular Strength

Drug Facts

Active ingredients

(in each 30 mL dose)

Aluminum hydroxide 1200 mg

(equivalent to dried gel, USP)

Magnesium hydroxide 1200 mg

Simethicone 120 mg

Purposes

Aluminum hydroxide.....Antacid

(equivalent to dried gel, USP)

Magnesium hydroxide.....Antacid

Simethicone.....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. Antacid may interact with certain prescription drugs.

When using this product

- do not take more than 120 mL (4 doses) in a 24-hour period
- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Directions

- shake well before use
- adults and children 12 years and older: 30 mL (1 dose) up to 4 times a day or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- **each 30 mL contains:** magnesium 510 mg, sodium 18 mg
- store at 20-25°C (68-77°F)
- protect from freezing
- keep tightly closed
- **tamper-evident: do not use if foil on cup is missing or torn**

Inactive ingredients

benzyl alcohol, butylparaben, flavor (contains alcohol), hydroxyethyl cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

Questions or comments?

Call 1-888-655-1505

How Supplied

Alumina, Magnesia, and Simethicone Oral Suspension is a white suspension supplied as follows:

NDC 66689-060-01: 30 mL unit-dose cup

NDC 66689-060-99: Case contains 100 unit-dose cups of 30 mL (NDC 66689-060-01), packaged in 10 trays of 10 unit-dose cups each.

Distributed by:

VistaPharm Inc.

Largo, FL 33771, USA

VP2184

05/20

Principal Display Panel

REGULAR STRENGTH

Alumina, Magnesia, and

Simethicone Oral Suspension

each 30 mL contains:

Aluminum Hydroxide Gel.....1200 mg

Magnesium hydroxide.....1200 mg

Simethicone.....120 mg

Alcohol 0.15%

Delivers 30 mL

Store at 20°-25°C (68°-77°F). Shake Well

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Rev.06/20

NDC 66689-060-01



ALUMINA, MAGNESIA, AND SIMETHICONE ORAL SUSPENSION REGULAR STRENGTH

alumina, magnesia, and simethicone oral suspension regular strength suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66689-060
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 HYDROXIDE	1200 mg in 30 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	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)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	WHITE (white suspension)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66689-060-99	100 in 1 CASE	09/15/2020	
1	NDC:66689-060-01	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	09/15/2020	

Labeler - VistaPharm, Inc. (116743084)

Revised: 9/2020

VistaPharm, Inc.