

**MAG-AL PLUS- aluminum hydroxide, magnesium hydroxide, and simethicone suspension
Pharmaceutical Associates, 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.

Mag-AL Plus

Drug Facts

Active ingredients (in each 5 mL = 1 teaspoonful)	Purpose
Aluminum hydroxide (equiv. to dried gel, USP) 200 mg	Antacid
Magnesium hydroxide 200 mg	Antacid
Simethicone 20 mg	Antigas

Uses

for the relief of:

- acid indigestion
- heartburn
- sour stomach
- upset stomach due to these symptoms
- pressure and bloating commonly referred to as gas

Warnings

Do not take more than 16 teaspoonfuls in a 24-hour period or use the maximum dosage for more than 2 weeks except under the advice and supervision of a physician.

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are presently 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.

Directions

- shake well before using
- do not take more than 16 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks

adults and children 12 years and older	take 2 to 4 teaspoonfuls four times a day or as directed by a physician
children under 12 years	consult a physician

Other information

- **each 5 mL contains:** magnesium 83 mg, sodium 1.34 mg
- store at controlled room temperature 20° - 25°C (68° - 77°F)
- protect from freezing
- White colored, peppermint flavored liquid supplied in the following oral dosage form:

NDC 0121-1761-30 30 mL unit dose cup. Case contains
30: 100 unit dose cups of 30 mL packaged
in 10 trays of 10 unit dose cups each.

Inactive ingredients

Butylparaben, hydroxypropyl methylcellulose, flavoring, propylene glycol, propylparaben, purified water, sodium saccharin, and sorbitol solution.

Questions or comments?

Call 1-800-845-8210

MANUFACTURED BY

***Pharmaceutical
Associates, Inc.***

Greenville, SC 29605

PRINCIPAL DISPLAY PANEL - 30 mL Unit-Dose Cup Tray Label

Delivers **30 mL**

NDC 0121-1761-30

MAG-AL PLUS

Each 30 mL contains:

Aluminum Hydroxide 1200 mg

Magnesium Hydroxide 1200 mg

Simethicone 120 mg

SHAKE WELL

USUAL DOSAGE: See attached Drug Facts

Package Not Child-Resistant

Pharmaceutical Associates, Inc.
Greenville, SC 29605

SEE INSERT



MAG-AL PLUS

aluminum hydroxide, magnesium hydroxide, and simethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-1761
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	200 mg in 5 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	

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:0121-1761-30	10 in 1 CASE	01/14/2004	
1		10 in 1 TRAY		
1		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	01/14/2004	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-1761)