

**MILK OF MAGNESIA- magnesium hydroxide suspension**  
**PAI Holdings, LLC**

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**Milk of Magnesia**

***Drug Facts***

**Active ingredient (in each 5 mL)**

Magnesium hydroxide 400 mg

**Purpose**

Saline laxative

**Uses**

**As an Antacid**

- heartburn
- upset/sour stomach
- acid indigestion

**As a Laxative (usually within ½ to 6 hours)**

- occasional constipation (irregularity)

**Warnings**

**Ask a doctor before use if you have**

- kidney disease
- a magnesium-restricted diet
- stomach pain, nausea, or vomiting
- a sudden change in bowel habits that lasts over 14 days

**Ask a doctor or pharmacist before use If you are** taking a prescription drug. This product may interact with certain prescription drugs.

**Stop use and ask a doctor if**

- you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

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

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

### As an Antacid

- do not exceed the maximum recommended daily dose in a 24 hour period
- shake well before use
- can be taken with water
- mL = milliliter

adults and children 12 years of age and over	5 to 15 mL (1 to 3 teaspoonfuls)
children under 12 years of age	ask a doctor

### As a Laxative

- do not exceed the maximum recommended daily dose of 60 mL in a 24 hour period
- shake well before use
- dose may be taken once a day preferably at bedtime, in divided doses, or as directed by a doctor. Drink a full glass (8 oz) of liquid with each dose.
- mL = milliliter; TBSP = Tablespoon

adults and children 12 years and older	30 mL (2 TBSP) to 60 mL (4 TBSP)
children 6 - 11 years	15 mL (1 TBSP) to 30 mL (2 TBSP)
children under 6 years	ask a doctor

### Other information

- **each teaspoonful (5 mL) contains:** magnesium 400 mg
- store at room temperature, 20° - 25°C (68° - 77°F). Avoid freezing.
- Milk of Magnesia USP (white suspension, spearmint flavor) is supplied in the following oral dosage form:

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NDC 0121-0431-30: 30 mL unit dose cup. Case contains 100 unit dose cups of 30 mL packaged in 10 trays of 10 unit dose cups each.

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### Inactive ingredients

flavoring, hydroxypropyl methylcellulose, methylparaben, potassium citrate, propylene glycol, propylparaben, purified water, antifoam af emulsion, sodium saccharin, and sorbitol.

### Questions or comments?

**Call 1-800-845-8210**

**MANUFACTURED BY**

**Pharmaceutical  
Associates, Inc.**  
Greenville, SC 29605

**PRINCIPAL DISPLAY PANEL - 30 mL Cup Tray Label**

NDC 0121-0431-30

**Milk of Magnesia USP**  
ANTACID, SALINE LAXATIVE

Each 30 mL contains:

Magnesium Hydroxide  
2400 mg

**SHAKE WELL**

**USUAL DOSAGE:** See attached Drug Facts

Package Not Child-Resistant

*Pharmaceutical Associates, Inc.*

Greenville, SC 29605

F0431300721



## MILK OF MAGNESIA

magnesium hydroxide suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0121-0431
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MAGNESIUM HYDROXIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	400 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSE 2910 (4000 MPA.S)</b> (UNII: RN3152OP35)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 4</b> (UNII: CZ227117JE)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	SPEARMINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0431-30	10 in 1 CASE	09/04/1979	
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 Drug	M007	09/04/1979	

**Labeler** - PAI Holdings, LLC (044940096)

### Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	manufacture(0121-0431)

Revised: 1/2022

PAI Holdings, LLC