

MILK OF MAGNESIA- magnesium hydroxide suspension
PAI Holdings, LLC

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:

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.

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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

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

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

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: 11/2024

PAI Holdings, LLC