MILK OF MAGNESIA- magnesium hydroxide 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.

MILK OF MAGNESIA

CONCENTRATE

Drug Facts

Active ingredient (in each 10 mL)

Magnesium hydroxide 2400 mg

Purpose

Saline laxative

Uses

As an Antacid
- heartburn
- upset/sour stomach
- acid indigestion

As a Laxative
- relieves occasional constipation (irregularity) This product usually produces bowel movement in ½ to 6 hours.

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients

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 of 20 mL 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 mL (1 teaspoonful)
children under 12 years of age	ask a doctor

As a Laxative

- do not exceed the maximum recommended daily dose 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

adults and children 12 years and older	15 mL to 30 mL
children under 12 years	ask a doctor

Other information

- **each teaspoonful (5 mL) contains:** magnesium 1000 mg
- Sodium Content: 19 mg/10 mL
- store at room temperature, 20° - 25°C (68° - 77°F). Avoid freezing.
- Milk of Magnesia Concentrate (white suspension, lemon flavored) is supplied in the following oral dosage form:

NDC 0121-0527-10: 10 mL unit dose cup. Case contains 100 unit dose cups of 10 mL packaged in 10 trays of 10 unit dose cups each.

Inactive ingredients

antifoam af emulsion, flavoring, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sodium saccharin, sodium salts of polymerized alkylnaphthalenesulfonic acid, sorbitol, and sucrose.

Questions or comments?

Call 1-800-845-8210

MANUFACTURED BY

Pharmaceutical
Associates, Inc.
Greenville, SC 29605
www.paipharma.com

R03/18

PRINCIPAL DISPLAY PANEL - 10 mL Unit-Dose Cup Tray Label

NDC 0121-0527-10

Milk of Magnesia Concentrate

ANTACID/ SALINE LAXATIVE

Each 10 mL contains:

Magnesium Hydroxide
2400 mg

SHAKE WELL

USUAL DOSAGE: See attached Drug Facts

This unit-dose package is not child-resistant.

Store at 20° - 25°C (68° - 77°F)
[See USP Controlled Room Temperature].

Protect from freezing.

10 x 10 mL Unit-Dose Cups

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Associates, Inc.
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T0527100318
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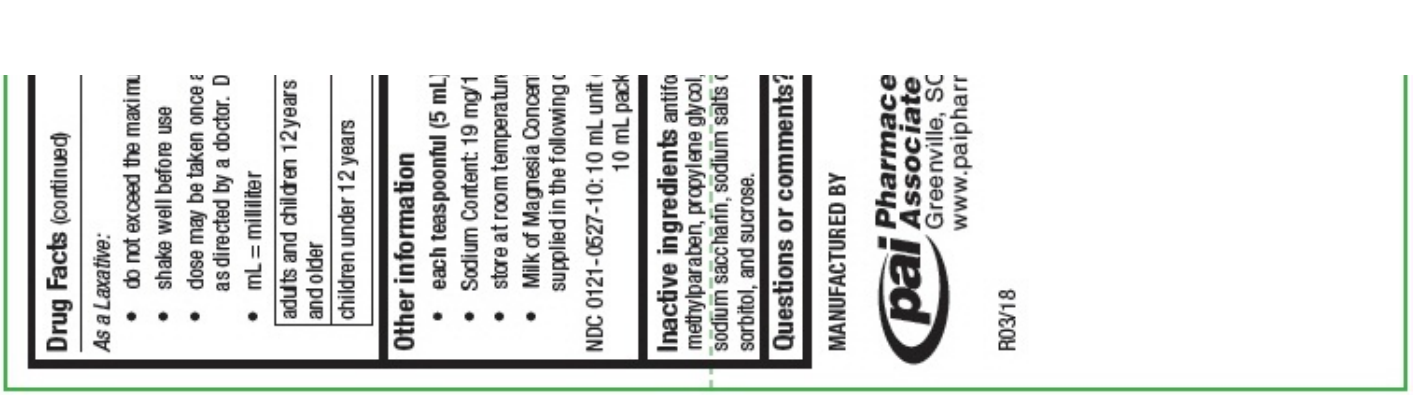

MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0527
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	2400 mg in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
FORMALDEHYDE/SODIUM NAPHTHALENESULFONATE COPOLYMER (3000 MW) (UNII: 90D834OZUI)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor	LEMON	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0527-10	10 in 1 CASE	04/20/1982	
1		10 in 1 TRAY		
1		10 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	04/20/1982	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0527)

Revised: 5/2018 Pharmaceutical Associates, Inc.