

MILK OF MAGNESIA CONCENTRATE- magnesium hydroxide suspension
PAI Holdings, LLC dba PAI Pharma

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 0121-0940-10: 10 mL unit dose cup, in a tray of ten cups.

Inactive ingredients

glycerin, hydroxypropyl methylcellulose, lemon oil, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, sodium saccharin, sorbitol, and sucrose.

Questions or comments?

Call 1-800-845-8210

MANUFACTURED BY

**Pharmaceutical
Associates, Inc.**

Greenville, SC 29605
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R07/21

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

NDC 0121-0940-10

Milk of Magnesia Concentrate

Each 10 mL contains:

Magnesium Hydroxide 2400 mg.

ANTACID/ SALINE LAXATIVE

SHAKE WELL

Package Not Child-Resistant

See Insert



MILK OF MAGNESIA CONCENTRATE

magnesium hydroxide suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-0940
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KOOR)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	LEMON (LEMON-OIL)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0940-00	10 in 1 CASE	01/18/2022	
1		10 in 1 TRAY		
1	NDC:0121-0940-10	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 Drug	M007	01/18/2022	

Labeler - PAI Holdings, LLC dba PAI Pharma (044940096)

Establishment

Business

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	manufacture(0121-0940)

Revised: 11/2024

PAI Holdings, LLC dba PAI Pharma