

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

-----  
**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  
www.paipharma.com

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**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0121-0940 |
| <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 | 2400 mg in 10 mL |

## Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)   |          |
| <b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K) |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)            |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)               |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)               |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                    |          |
| <b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)           |          |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)            |          |
| <b>SUCROSE</b> (UNII: C151H8M554)                     |          |
| <b>WATER</b> (UNII: 059QF0KOOR)                       |          |

## Product Characteristics

|                 |                   |                     |  |
|-----------------|-------------------|---------------------|--|
| <b>Color</b>    | white             | <b>Score</b>        |  |
| <b>Shape</b>    |                   | <b>Size</b>         |  |
| <b>Flavor</b>   | LEMON (LEMON-OIL) | <b>Imprint Code</b> |  |
| <b>Contains</b> |                   |                     |  |

## 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 (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: 2/2022

PAI Holdings, LLC