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.

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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
• Milk of Magnesia USP (white suspension, spearmint flavor) is supplied in the following oral dosage form:

30 mL unit dose cup. Case contains 100 unit dose

NDC 0121-0431-30: 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

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 30 mL Unit-Dose Cups

Pharmaceutical Associates, Inc.
Greenville, SC 29605
T0431300318
R03/18
Milk of Magnesia USP
ANTACID/SALINE LAXATIVE

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Pai Pharmaceutical Associates, Inc.
Greenville, SC 29605

T0431300318 R03/18

Drug Facts

<table>
<thead>
<tr>
<th>Active ingredient (in each 5 mL)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium hydroxide 400 mg</td>
<td>Saline laxative</td>
</tr>
</tbody>
</table>

Uses
- As an Antacid
- As a Laxative (usually within 1/2 to 6 hours)
- As an Antidiarrheal
- As a Laxative (usually within 1/2 to 6 hours)

Warnings
- Ask a doctor before use if you have:
  - Heartburn
  - Upset/or stomach
  - Acid indigestion
  - Occasional constipation (irregularity)

- Ask a doctor before use if you have:
  - Kidney disease
  - Stomach pain, nausea, or vomiting
  - Stomach pain, nausea, or vomiting

- Ask a doctor before use if you are taking a prescription drug.

- Ask a doctor before use if you are taking any non-prescription drugs.

Dose
- Adults and children 12 years of age or over: keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use.

Directions
- Adults and children 12 years of age or over: take 1 mL (1/4 teaspoonful) for every 100 mL (1 cup) of liquid with each dose.
- Children under 12 years of age: ask a doctor.

Ingredients:
- Active ingredient: magnesium hydroxide 400 mg.
- Other ingredients: water, glycol, propylene glycol, purified water, and sodium acryloyldimethyltaurate/AM/50 emulsion, and color additives.

Specifications:
- 0.845-8201 mg/ml
- 100 unit dose cups per case.
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

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)</td>
<td>MAGNESIUM HYDROXIDE</td>
<td>400 mg in 5 mL</td>
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Inactive Ingredients

<table>
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<th>Ingredient Name</th>
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<tr>
<td>HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)</td>
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<tr>
<td>METHYLPARABEN (UNII: A2BC7HB9T)</td>
</tr>
<tr>
<td>POTASSIUM CITRATE (UNII: EE90ON66FF)</td>
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<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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<tr>
<td>CYCLOMETHICONE 4 (UNII: CZ227117JE)</td>
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<tr>
<td>PROPYLPARABEN (UNII: Z8JX2SC1OH)</td>
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<tr>
<td>SORBITOL (UNII: 506T60A25R)</td>
</tr>
<tr>
<td>SACCHARIN SODIUM (UNII: SB8ZUX40TY)</td>
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Product Characteristics

| Color | white |
| Shape | |
| Flavor | SPEARMINT |
| Contains | |

Packaging
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<th>#</th>
<th>Item Code</th>
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<th>Marketing End Date</th>
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<td>1</td>
<td>NDC:0121-0431-30</td>
<td>10 in 1 CASE</td>
<td>09/04/1979</td>
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<tr>
<td>1</td>
<td></td>
<td>10 in 1 TRAY</td>
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<tr>
<td>1</td>
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<td>30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product</td>
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### Marketing Information

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<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>OTC monograph final</td>
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### Labeler

Pharmaceutical Associates, Inc. (044940096)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Pharmaceutical Associates, Inc.</td>
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<td>097630693</td>
<td>manufacture(0121-0431)</td>
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Revised: 6/2018