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

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>adults and children 12</td>
<td>5 mL (1</td>
</tr>
<tr>
<td>years of age and over</td>
<td>teaspoonful)</td>
</tr>
<tr>
<td>children under 12 years</td>
<td>ask doctor</td>
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<tr>
<td>of age</td>
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</table>

**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

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<thead>
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<tbody>
<tr>
<td>adults and children 12</td>
<td>15 mL to</td>
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<tr>
<td>years and older</td>
<td>30 mL</td>
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<tr>
<td>children under 12 years</td>
<td>ask a</td>
</tr>
<tr>
<td>of age</td>
<td>doctor</td>
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**Other information**
- each teaspoonful (5 mL) contains: magnesium 1000 mg
- Sodium Content: 19 mg/10 mL
- 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 alkynaphthalenesulfonic acid, sorbitol, and sucrose.

**Questions or comments?**

Call 1-800-845-8210

**MANUFACTURED BY**

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

Pharmaceutical
Associates, Inc.
Greenville, SC 29605

T0527100318
R03/18
Milk of Magnesia Concentrate
ANTACID/ SALINE LAXATIVE
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SHAKE WELL

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

Protect from freezing.
10 x 10 mL Unit-Dose Cups

Drug Facts

Active ingredient
Magnesium hydroxide 2400 mg

Uses
As an Antacid
Heartburn
Upset/stomach
acid indigestion

As a Laxative
relieves occasional constipation (irregularity). This product usually produces bowel movement in 3 to 7 hours.

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

As needed
Do not use if you have diarrhea.

Stop use and ask a doctor if:
• you have fever with mouth ulcers
• diarrhea is severe, does not improve, or lasts more than 2 days
• in children under 12 years of age

Ask a doctor before use if you are taking any other drugs.

Keep out of reach of children.

DIRECTIONS
As an Antacid:
• Do not exceed the maximum recommended daily dose of 20 mL in a 24 hour period.
• 1 to 3 doses daily, as needed, in divided doses, or
• 0 mL, if you prefer

Call 1-800-945-8210

Pharmaceutical Associates, Inc.
Greenville, SC 29605
T527100318 R03/18
MILK OF MAGNESIA
magnesium hydroxide suspension

Product Information

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<td>HUMAN OTC DRUG</td>
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Route of Administration

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<tr>
<th>Route of Administration</th>
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<tbody>
<tr>
<td>ORAL</td>
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Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>MAGNESIUM HYDROXIDE</td>
<td>MAGNESIUM HYDROXIDE</td>
<td>2400 mg in 10 mL</td>
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Inactive Ingredients

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<td>GLYCERIN</td>
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<tr>
<td>METHYL PARABEN</td>
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<tr>
<td>PROPYL PARABEN</td>
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<tr>
<td>PROPYLENE GLYCOL</td>
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<tr>
<td>SODIUM CITRATE, UNSPECIFIED FORM</td>
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<td>SACCHARIN SODIUM</td>
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<td>SORBITOL</td>
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<tr>
<td>SUCROSE</td>
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<tr>
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<td>CYCLOMETHICONE 4</td>
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<td>WATER</td>
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Product Characteristics

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<td>LEMON</td>
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Packaging
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<td>04/20/1982</td>
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<td>1</td>
<td></td>
<td>10 in 1 TRAY</td>
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<tr>
<td>1</td>
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<td>10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product</td>
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### Marketing Information

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<td>OTC monograph final</td>
<td>part331</td>
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### Labeler
- Pharmaceutical Associates, Inc. (044940096)

### Establishment

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<th>Name</th>
<th>Address</th>
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<td>097630693</td>
<td>manufacture(0121-0527)</td>
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Revised: 5/2018