**MILK OF MAGNESIA- milk of magnesia concentrate**
**West-Ward Pharmaceuticals Corp.**

*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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**Drug Facts**

***CONCENTRATED* Milk of Magnesia (Lemon Flavored)**

**Drug Facts**

| **Serving Size: 10 mL (2 teaspoonful)** | |
|---|---|
| **Active Ingredient (per 10 mL)** | **Purpose** |
| Magnesium hydroxide 2400 mg | Laxative |

**Active Ingredient per 10 mL**

Magnesium hydroxide 2400 mg

**Purpose**

Laxative

**Keep Out of Reach of Children**

**Warnings**

**Ask a doctor before us if you have:**

- Kidney disease
- Stomach pain, nausea or vomiting
- A magnesium restricted diet
- A sudden change in bowel habits that lasts over 14 days

**Ask a doctor or pharmacist before use if you are** taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

**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 one week.

**If pregnant or breast-feeding,** ask a health professional before use.

In case of overdose, get medical help or contact a Poison Control Center right away.

This package bears a tamper evident seal. If the seal is broken, do not use.

**Suggested Uses**

- Relieves occasional constipation (irregularity).

This product usually produces bowel movement in 1/2 to 6 hours.

**Directions**

- Shake well before use – Do not dilute.
- Do not exceed the maximum recommended daily dose in a 24 hour period.
- 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.

| | |
|---|---|
| Adults and Children 12 Years and Older | 10 to 20 mL (2 to 4 tsp.) |
| Children 6 to 11 Years | 5 to 10 mL (1 to 2 tsp.) |
| Children under 6 Years | Ask a Doctor |

**Other Information**

- 10 mL contains: magnesium 1000 mg
- 10 mL contains: sodium 21 mg

**Storage and Handling**

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

Do not freeze, keep tightly closed.

**Inactive Ingredients**

Benzyl alcohol, carboxymethylcellulose sodium, citric acid anhydrous, glycerin, lemon oil, purified water, sodium citrate, sodium hexametaphosphate, sodium hyprochlorite, sorbitol, sucrose, vanillin.

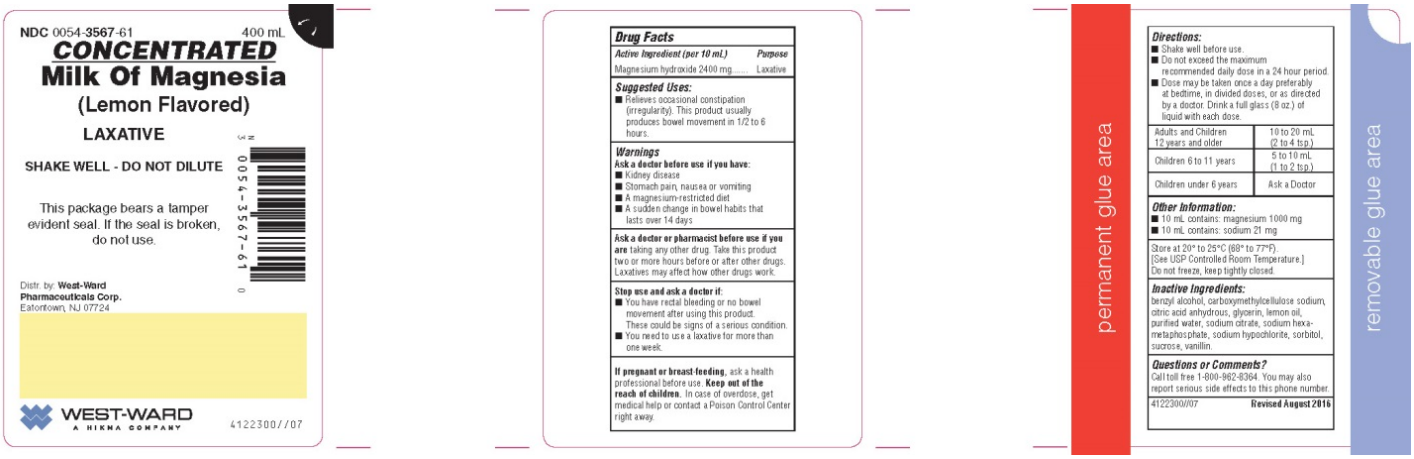
**Questions or Comments?**

Call toll free 1-800-962-8364. You may also report serious side effects to this phone number

Distr. by: **West-Ward**
**Pharmaceutical Corp.**
Eatontown, NJ 07724

**Revised August 2016**

**Package/Label Principal Display Panel**




**CONCENTRATED Milk of Magnesia (Lemon Flavored)**

0054-3567-61: Bottles of 400 mL

# MILK OF MAGNESIA

milk of magnesia concentrate

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0054-3567 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MAGNESIUM HYDROXIDE** (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM HYDROXIDE | 2400 mg in 10 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BENZYL ALCOHOL** (UNII: LKG8494WBH) | |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **LEMON OIL** (UNII: I9GRO824LL) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM POLYMETAPHOSPHATE** (UNII: P1BM4ZH95L) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **VANILLIN** (UNII: CHI530446X) | |
| **SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR) | |
| **CARBOXYMETHYLCELLULOSE** (UNII: 05JZI7B19X) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |

| | | | | |
|---|---|---|---|---|
| **1** | NDC:0054-3567-49 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/12/2001 | |
| **2** | NDC:0054-3567-61 | 400 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/12/2001 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part334 | 03/12/2001 | |

## Labeler - West-Ward Pharmaceuticals Corp. (080189610)

## Registrant - Roxane Laboratories, Inc. (833490464)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| West-Ward Columbus Inc. | | 058839929 | MANUFACTURE(0054-3567) |

Revised: 5/2015 West-Ward Pharmaceuticals Corp.