MILK OF MAGNESIA- milk of magnesia suspension Cardinal Health

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.

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 ¹/₂ 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 | 5 mL (1 teaspoonful) |
|-------------------------|----------------------|
| years of age and over | |
| children under 12 years | ask a doctor |
| of age | |

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 | 15 mL to 30 mL |
|-------------------------|----------------|
| years and older | |
| 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 0121-0527-10: 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 alkylnaphthalenesulfonic acid, sorbitol, and sucrose.

Questions or comments?

Call 1-800-845-8210

MANUFACTURED BY

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

Distributed by: Cardinal Health

Dublin, OH 43017

L33755080318

R03/18

Principal Display Panel

Milk of Magnesia Concentrate

5 Cups



H30

MILK OF MAGNESIA CONCENTRATE

5 CUPS

Delivers 10 mL Each 10 mL contains: Magnesium Hydroxide 2400 mg.

Antacid, Saline Laxative

SHAKE WELL

See product insert for prescribing information, precautions and warnings.

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

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

PHARMACEUTICAL ASSOCIATES, INC. Subsidiary of Beach Products, Inc. 201 Delaware Street GREENVILLE, SC 29605 (800) 845-8210 www.paipharma.com DURA-DOSE®

Distributed by Cardinal Health Dublin, OH 43017 L33755080318

LOT #: XXXXXXXXXX EXP. DATE: XX/XX/XX

| Product Inform | | | | | |
|--|--|--|-------------------|-------------------------------------|-----------------------|
| Product Inform | ation | | | | |
| Product T ype | | HUMAN OTC DRUG | Item Code (Source |) NDC:55154-9412 | (NDC:0121-0527) |
| Route of Administ | ration | ORAL | | | |
| | | | | | |
| Active Ingredie | nt/Active Mo | iety | | | |
| Ingredient Name Basis of Strength | | | | | |
| MAGNESIUM HYDR UNII:T6 V3LHY8 38) | SIUM HYDRO XIDE (UNII: NBZ3Q Y004S) (MAGNESIUM CATION - /3LHY838) | | | MAGNESIUM HYDRO XIDE | 2400 mg in 10 mL |
| Inactive Ingred | ients | | | | |
| | | Ingredient Na | me | | Strength |
| GLYCERIN (UNII: PI | DC6A3C0OX) | | | | |
| METHYLPARABEN | (UNII: A218C7HI9 | T) | | | |
| PROPYLENE GLYC | OL (UNII: 6DC9 | Q167V3) | | | |
| PROPYLPARABEN | (UNII: Z8IX2SC10 | OH) | | | |
| WATER (UNII: 059Q | F0KO0R) | | | | |
| SODIUM CITRATE, | UNSPECIFIED F | ORM (UNII: 1Q73Q2JULR) | | | |
| SACCHARIN SODIU | M (UNII: SB8ZU | X40TY) | | | |
| PYRROBUTAMINE | NAPHTHALENE | DISULFONATE (UNII: 144 | X0H6HW6) | | |
| SORBITOL (UNII: 5 | | | | | |
| SUCROSE (UNII: C1 | 51H8M554) | | | | |
| | | | | | |
| Product Charac | teristics | | | | |
| Color | | WHITE | Score | | |
| Shape | | | Size | | |
| Flavor | | LEMON | Imprint Code | | |
| Contains | | | - | | |
| | | | | | |
| | | | | | |
| Packaging | | | | | |
| | | Package Description | | Marketing Start Date | - |
| Packaging # Item Code 1 NDC:55154-9412- | 5 in 1 BAG | Package Description | | Marketing Start Date /07/2011 | Marketing End Date |
| # Item Code 1 NDC:55154-9412- | | Package Description UNIT-DOSE; Type 0: Not a | 06 | Date | - |
| # Item Code 1 NDC:55154-9412- 5 | 10 mL in 1 CUP, | | 06 | Date | - |
| # Item Code 1 NDC:55154-9412- 5 | 10 mL in 1 CUP, Product | | 06 | Date | - |

Labeler - Cardinal Health (603638201)

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