

MILK OF MAGNESIA- magnesium hydroxide suspension
Rising Pharma Holdings, 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.

Milk of Magnesia 2400 mg/30 mL

Drug Facts

Active ingredient per 30mL (1 Unit Dose)

Magnesium hydroxide 2,400 mg

Purpose

Saline laxative

Uses

- relieves occasional constipation (irregularity)
- usually produces bowel movement in ½ hour to 6 hours

Warnings

Ask a doctor before use if you have • Kidney disease • a magnesium-restricted diet
• Stomach pain • 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 may 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 accidental overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- shake well before use
- 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 (8oz) of liquid with each dose

age	dose
Adults and children over 12 years of age	Take 30mL (one unit dose) to 60mL (2 unit dose)
Children under 12 years of age	Ask a doctor

Other information

- **each 30 mL (unit dose) contains** Magnesium 1000 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- protect from freezing
- do not use if lid is torn or broken

Inactive ingredients purified water, and sodium hypochlorite.

NDC Information -

2400 mg/30 mL

Each 30 mL of Milk of Magnesia contains Magnesium hydroxide 2,400mg and is supplied in the following oral dosage forms:

NDC 57237-314-03 unit dose cup 30mL

NDC 57237-314-31 (100x30) unit dose cups 30mL

Questions or comments?Call 1-844-474-7464

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

FG-37/Iss.: 04/2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

2400 mg/30 mL

Lid Label NDC 57237-314-03

Delivers 30 mL
Milk of Magnesia
Saline Laxative
2400 mg/30 mL

Shake Well | For Institutional Use Only | See Label

Dist. By: Rising Pharma Holdings, Inc. NJ 08816

Iss. 05/2023 FG-37



5723731403

Exp. yyyy/mm Lot# XXXXXX



1

2400 mg/30 mL

Case Label NDC 57237-314-31

NDC 57237-314-31

Milk of Magnesia

Saline Laxative

2400 mg/30 mL

USUAL DOSAGE: See attached Drug Facts

FOR INSTITUTIONAL USE ONLY

100 x 30 mL Unit-Dose Cups

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NDC 57237-31431-9

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NDC 57237-314-31

NDC 57237-31431-9

Milk of Magnesia

2400 mg/30 mL

100 x 30 mL Unit-Dose Cups

LOT#

Exp. Date:

Unvarnished Area

MILK OF MAGNESIA
 magnesium hydroxide suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-314
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	2400 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-314-31	100 in 1 BOX, UNIT-DOSE	07/05/2023	
1	NDC:57237-314-03	30 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 final	part331	07/05/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 7/2023

Rising Pharma Holdings, Inc.