

MILK OF MAGNESIA- magnesium hydroxide liquid
RIJ Pharmaceutical Corporation

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.

Drug Facts

Active Ingredient (in each 15 mL Tablespoon)

Magnesium Hydroxide 1200 mg

Purpose

Saline laxative

Use

- relieves occasional constipation (irregularity).
- This product generally produces bowel movement in ½ to 6 hours.

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 more than 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 one 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

- 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, TBSP = Tablespoonful

adults and children 12 years and older	30 mL (2 TBSP) to 60 mL (4 TBSP)
children 6 to 11 years	15 mL (1 TBSP) to 30 mL (2 TBSP)
children under 6 years	ask a doctor

Other information

- TAMPER EVIDENT: Do not use if breakaway band on cap is broken or missing.
- Store at room temperature 15° - 30°C (59° - 86°F)
- keep tightly closed
- keep from freezing
- each tablespoon (15 mL) contains: magnesium 498 mg
- each tablespoon (15 mL) contains: sodium 3 mg

Inactive ingredients

citric acid, purified water, sodium hypochlorite

Principal Display Panel



NDC 53807-125-16

Compare to the Active Ingredient in Phillip's Milk of Magnesia®†

MILK OF Magnesia

LAXATIVE

For the Relief of:

- Constipation

ORIGINAL

16 FL OZ (473 mL)

Drug Facts

Active Ingredient (in each 15 ml Tablespoon)	Purpose
Magnesium Hydroxide 1200 mg	Saline laxative

Use relieves occasional constipation (irregularity). This product usually produces bowel movement in 1/2 to 6 hours.

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 one 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

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- 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.
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- each tablespoon (15 mL) contains : magnesium 498 mg
- each tablespoon (15 mL) contains: sodium 3 mg

Inactive ingredient: citric acid, purified water, sodium hypochlorite.

†This product is not manufactured or distributed by the owner of the registered trademark Phillips' Milk of Magnesia.

RIJ PHARMACEUTICAL CORP.
40 Commercial Avenue
Middletown, NY 10941

Rev. 03/13



MILK OF MAGNESIA

magnesium hydroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-125
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDRO XIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	1200 mg in 15 mL
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Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)	

Product Characteristics

Color	WHITE (opaque)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-125-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-125-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
3	NDC:53807-125-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/16/1999	

Labeler - RIJ Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
RIJ Pharmaceutical Corporation		144679156	manufacture(53807-125)