

MILK OF MAGNESIA- magnesium hydroxide liquid

Kinray LLC

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 5 mL Tablespoon)

Magnesium Hydroxide 400 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
- stomach pain, nausea, or vomiting
- a sudden change in bowel habits that persist over a period of 2 weeks
- a magnesium - restricted diet

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

- 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 (8 oz) of liquid with each dose
- mL = milliliter, TBSP = Tablespoonful

adults and children 12 years and older	2 to 4 Tbsp.
children 6 to 11 years	1 to 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 (5 mL) contains: sodium 4 mg
- each tablespoon (5 mL) contains: magnesium 166 mg

Inactive ingredients

carboxymethylcellulose sodium, citric acid, D&C red #28, flavor, glycerin, microcrystalline cellulose, water, sodium citrate, sodium hypochlorite, sucrose, xanthan gum.

Principal Display Panel


NDC 61715-131-04



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

MILK OF Magnesia

LAXATIVE
For the Relief of:
• Constipation



CHERRY


12 FL OZ (355 mL)

Drug Facts	Purpose Magnesium Hydroxide 400 mg Saline laxative						
Active ingredient (in each 5 mL)(One teaspoonful)							
Uses	<ul style="list-style-type: none"> ■ relieves occasional constipation (irregularity) ■ generally produces bowel movement in 1/2 to 6 hours 						
Warnings	<p>Ask a doctor before use if you have ■ kidney disease</p> <p>■ stomach pain, nausea or vomiting ■ notice a sudden change in bowel habits that persists over a period of 2 weeks ■ a magnesium - restricted diet</p> <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacid may interact with certain prescription drugs.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ you have rectal bleeding or failure to have a bowel movement after use. These may indicate a serious condition ■ you need to use a laxative for more than one week <p>if pregnant or breast-feeding, ask a health professional before use</p> <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center immediately.</p> <p>Directions • shake well before use</p> <ul style="list-style-type: none"> • 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. <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 50%;">adults and children 12 years and older</td> <td style="width: 50%;">2 to 4 Tbsp.</td> </tr> <tr> <td>children 6 to 11 years</td> <td>1 to 2 Tbsp.</td> </tr> <tr> <td>Children under 6 years</td> <td>ask a doctor</td> </tr> </table>	adults and children 12 years and older	2 to 4 Tbsp.	children 6 to 11 years	1 to 2 Tbsp.	Children under 6 years	ask a doctor
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Other information	<p>■ 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</p> <p>■ each teaspoon (5 mL) contains: sodium 4 mg</p> <p>■ each teaspoon (5 mL) contains: magnesium 166 mg</p> <p>Inactive ingredients: carboxymethylcellulose sodium, citric acid, D&C red #28, flavor, glycerin, microcrystalline cellulose, water, sodium citrate, sodium hypochlorite, sucrose, xanthan gum.</p> <p>Questions or comments? 1-845-692-5799</p>						

Manufactured By:
RLJ PHARMACEUTICAL CORP.
40 Commercial Avenue
Whitestone, NY 10941
Distributed by:
Kinray, Inc.,
Whitestone, NY 11357
L1Rev(11/08)

† This product is not manufactured or distributed by Bayer Corporation, owner of the registered trademark Philip's® Milk of Magnesia. All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

KIN 326-132



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MILK OF MAGNESIA

magnesium hydroxide liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:61715-131

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	400 mg in 5 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
	D&C RED NO. 28 (UNII: 767IP0Y5NH)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	WATER (UNII: 059QF0KO0R)			
	SODIUM CITRATE (UNII: 1Q73Q2JULR)			
	SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)			
	SUCROSE (UNII: C151H8M554)			
	XANTHAN GUM (UNII: TTV12P4NEE)			
Product Characteristics				
Color	PINK (PINK)	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-131-04	355 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	10/01/2014		

Labeler - Kinray LLC (012574513)