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

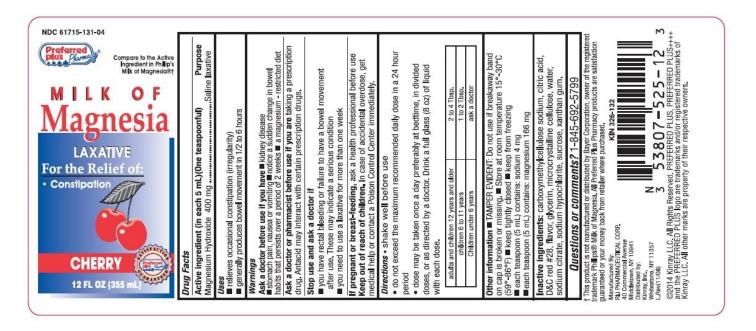
Other information

- 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



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 HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	400 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
D&C RED NO. 28 (UNII: 767IP0 Y5NH)		
GLYCERIN (UNII: PDC6A3C0OX)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
WATER (UNII: 059QF0KO0R)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SODIUM HYPOCHLORITE (UNII: DY38 VHM5OD)		
SUCROSE (UNII: C151H8 M554)		
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)

Revised: 10/2014 Kinray LLC