

MILK OF MAGNESIA- magnesium hydroxide suspension
LLC Federal Solutions

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.

Active ingredient (in each 15 mL tablespoonful)

Magnesium hydroxide 1200 mg

Purpose

Saline laxative

Uses

- relieves occasional constipation (irregularity)
- generally 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 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

- 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

adults and children 12 years and older: 2 to 4 tablespoonfuls (TBSP)

children 6 to 11 years: 1 to 2 tablespoonfuls (TBSP)

children under 6 years: ask a doctor

Other information

- **each 15 mL tablespoonful contains:** magnesium 500 mg
- store at room temperature and avoid freezing
- close cap tightly after use

Inactive ingredients

purified water, sodium hypochlorite

PRINCIPAL DISPLAY PANEL NDC: 24451-788-30

MILK OF MAGNESIA
DELIVERS 30 mL
CONTAINING:
MAGNESIUM HYDROXIDE
2400 mg
SALINE LAXATIVE
ORIGINAL FLAVOR
SUGAR FREE
SHAKE WELL
Exp: 00/00/00 Lot # 00000

Rpk By: Safecor Health LLC
Woburn, MA 01801
Dist. By: LLC Federal Solutions
Miami, FL 33132



MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24451-788(NDC:0904-0788)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24451-788-30	100 in 1 BOX		
1		30 mL in 1 CUP, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/12/2013	

Labeler - LLC Federal Solutions (965036895)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	repack(24451-788)

Revised: 8/2013

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