

MILK OF MAGNESIA MINT- magnesium hydroxide liquid

Chain Drug Marketing Association

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.

qc mom mint

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 more than 2 weeks

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 (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
- follow each dosage with a full glass (8 oz) of liquid

adults and children 12 years and over: 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 tablespoonful contains:** magnesium 500 mg
- store at room temperature and avoid freezing
- close cap tightly after use
- **TAMPER-EVIDENT: Do not use if imprinted neckband is missing or broken.**

Inactive ingredients

flavor, purified water, saccharin sodium, sodium hypochlorite

package label

NDC 63868-788-57



**Compare to the Active Ingredient In Phillips[®] Milk of Magnesia*

Milk of Magnesia

Saline Laxative

Effective Overnight Relief
Very Low Sodium
Stimulant Free
Sugar Free




REV 0414
231-19212-2

Mint Flavor


12 FL OZ (355 mL)

TAMPER-EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS MISSING OR BROKEN.

Drug Facts	Purpose
Active ingredient (in each 15 mL tablespoonful) Magnesium hydroxide 1200 mg	Saline laxative
Use	
<ul style="list-style-type: none"> • relieves occasional constipation (irregularity) • generally produces bowel movement in ½ to 6 hours 	
Warnings	
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • kidney disease • a magnesium-restricted diet • stomach pain, nausea or vomiting • a sudden change in bowel habits that lasts more than 14 days 	
<p>Ask a doctor or pharmacist before use if you are taking a prescription drug. This product 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 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 	
<p>if pregnant or breast-feeding, ask a health professional before use.</p>	
<p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<ul style="list-style-type: none"> • 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 	
age	dose
adults and children 12 years and over	2 to 4 tablespoonfuls (TBSP)
children 6 to 11 years	1 to 2 tablespoonfuls (TBSP)
children under 6 years	ask a doctor
Other information	
<ul style="list-style-type: none"> • each tablespoonful contains: magnesium 500 mg • store at room temperature • tightly closed do not freeze 	
Inactive ingredients flavor, purified water, saccharin sodium, sodium hypochlorite	
<p><small>*This product is not manufactured or distributed by Bayer Healthcare LLC, distributors of Phillips[®] brand Milk of Magnesia.</small></p>	



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 43157 W. Nine Mile
 Novi, MI 48376-0995
 www.qualitychoice.com
 Questions: 248-449-9300 931-19212-3 REV GC0619

MILK OF MAGNESIA MINT

magnesium hydroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-788
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	1200 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-788-57	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/01/2014	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - GCP Laboratories (965480861)

Establishment

Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(63868-788)