

MILK OF MAGNESIA ORIGINAL- 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

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

age	dose
adults and children 12 years and over	2 to 4 tablespoonfuls

children 6 to 11 years	1 to 2 tablespoonfuls
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

Inactive ingredients

purified water, sodium hypochlorite

package label

NDC 63868-787-57



*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

Original Flavor

12 FL OZ (355 mL)

REV 0618
231-19112-3

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 • relieves occasional constipation (irregularity) • 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 failure to have a 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 • follow each dosage with a full glass (8 oz) of liquid	
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Inactive ingredients purified water, sodium hypochlorite	

*This product is not manufactured or distributed by Bayer Healthcare LLC., distributors of Phillips[®] brand Milk of Magnesia.

Distributed by C.D.M.A., Inc.®
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Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-449-9300 931-19112-3 REV 060618



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-787
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: 059QF0KO0R)	
SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-787-57	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2018	

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(63868-787)