# TOPCARE MILK OF MAGNESIA- magnesium hydroxide suspension Topco Associates 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.

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## Topco Associates LLC. Milk of Magnesia Drug Facts

## Active ingredient (in each 15 mL)

Magnesium hydroxide 1200 mg

## Purpose

Saline laxative

#### Uses

- 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 2 weeks

## Ask a doctor or pharmacist before use if you are

taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

## 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

do not exceed the maximum recommended daily dose in a 24 hour period

- shake well before use
- 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
- for accurate dosing, use dose cup provided
- mL = milliliter

adults and children 12	30 mL to 60 mL
years and older	
children 6 to 11 years	15 mL to 30 mL
children under 6 years	ask a doctor

#### Other information

- each 15 mL contains: calcium 20 mg, magnesium 595 mg, and sodium 2 mg
- does not meet USP requirements for preservative effectiveness
- store at 20-25°C (68-77°F)
- close cap tightly after use
- avoid freezing

## **Inactive ingredients**

light mineral oil, peppermint oil, purified water, saccharin sodium

## Questions or comments?

1-888-423-0139

## **Principal Display Panel**

COMPARE TO PHILLIPS® FRESH MINT ACTIVE INGREDIENT

STIMULANT FREE

**OUR PHARMACISTS RECOMMEND** 

Genuine Milk of Magnesia

SALINE LAXATIVE MAGNESIUM HYDROXIDE, 1200 mg per 15 mL

Comfortable, Cramp Free Relief

Sugar Free

#1 Doctor Recommended Saline Laxative Active Ingredient

12 FL OZ (355 mL)

FRESH MINT FLAVOR



COMPARE TO PHILLIPS'® FRESH MINT ACTIVE INGREDIENT\*

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: 33240 88 F9

# Drug Facts L

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: 33540 PP BTO

ELK GROVE VILLAGE, IL 60007 ©TOPCO PERA0218 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com

**GLUTEN FREE** 

**✓** QUALITY GUARANTEED

\*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Phillips'® Fresh Mint.



## TOPCARE MILK OF MAGNESIA

magnesium hydroxide suspension

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-332

Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength		
<b>MAGNESIUM HYDRO XIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	1200 mg in 15 mL		

Inactive Ingredients			
Ingredient Name	Strength		
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)			
PEPPERMINT OIL (UNII: AV092KU4JH)			

Product Characteristics			
Color	WHITE (opaque)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

l	Packaging				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1	NDC:36800-332-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/13/19 9 3	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	0 1/13/19 9 3	

# Labeler - Topco Associates LLC (006935977)

Revised: 5/2018 Topco Associates LLC