

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.

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 years and older	30 mL to 60 mL
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, potassium 2 mg and sodium 3 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

anhydrous citric acid, D&C red #28, flavor, glycerin, purified water, sorbitol solution, sucrose, xanthan gum

Questions or comments?

1-888-423-0139

Principal Display Panel

STIMULANT FREE

Milk of Magnesia

SALINE LAXATIVE

MAGNESIUM HYDROXIDE, 1200 mg per 15 mL

Comfortable, cramp free relief

ALCOHOL 0.4%

CHERRY FLAVOR

COMPARE TO PHILLIPS'® WILD CHERRY active ingredient

12 FL OZ (355 mL)

#1 Doctor recommended saline laxative active ingredient

NDC 36800-949-40

STIMULANT FREE

GENUINE

Milk of Magnesia

SALINE LAXATIVE
MAGNESIUM HYDROXIDE,
1200 mg per 15 mL

- Comfortable, cramp free relief

ALCOHOL 0.4%
CHERRY FLAVOR




COMPARE TO
PHILLIPS'® WILD CHERRY
active ingredient*

#1 Doctor recommended saline laxative active ingredient*

12 FL OZ (355 mL)

: 94940 88 F8

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

Drug Facts

Active ingredient (in each 15 mL)	Purpose
Magnesium hydroxide 1200 mg.....	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 years and older	30 mL to 60 mL
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, potassium 2 mg and sodium 3 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 anhydrous citric acid, D&C red #28, flavor, glycerin, purified water, sorbitol solution, sucrose, xanthan gum

Questions or comments? 1-888-423-0139

: 94940 88 F8


*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Phillips'® Wild Cherry.

*In the U.S. Source: AlphaImpactRx

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO PER116 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com

GLUTEN FREE

QUALITY GUARANTEED



TOPCARE MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-949
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK (Opaque Light pink)	Score	
Shape		Size	
Flavor	CHERRY (wild cherry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-949-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/20/2006	

Labeler - Topco Associates LLC (006935977)