MILK OF MAGNESIA - magnesium hydroxide liquid Harris Teeter

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.

Drug Facts

Active ingredient (in each 15 mL Tablespoon)

Magnesium hydroxide USP 1200 mg

Purpose

Saline laxative

Use

relieves occasional constipation (irregularity). This product usually produces bowel movement in $\frac{1}{2}$ 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 (1-800-222-1222) right away.

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, only use the dosing cup provided
- do not use any other dosing device

• TBSP = Tablespoon, mL = milliliter

age	dose
adults and children 12 years and older	30 mL (2 TBSP) to 60 mL (4 TBSP)
children 6 to 11 years	15 mL (1 TBSP) to 30 mL (2 TBSP)
children under 6 years	ask a doctor

Other information

- each tablespoon (15 mL) contains: calcium 20 mg and magnesium 495 mg
- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F) and avoid freezing. Close cap tightly after use.

Inactive ingredients

flavor, purified water, saccharin sodium

Questions or comments?

1-855-274-4122

* This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Phillips'® Milk of Magnesia.

PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC, MATTHEWS, NC 28105

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 12 FL OZ (355 mL) Bottle

Harris Teeter_{TM}
SALINE LAXATIVE
MILK OF MAGNESIA

Each 15 mL (1TBSP) dose of oral solution contains: 1200 mg magnesium hydroxide USP

- Stimulant Free
- Comfortable, Cramp-free Relief
- Sugar Free

Compare to the active ingredient in Phillips,® Milk of Magnesia* Mint Flavor

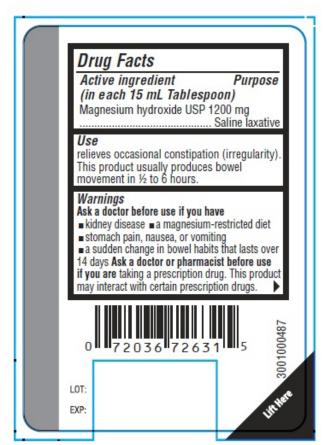
TAMPER-EVIDENT: Do not use if imprinted neckband is missing or broken. **12 FL OZ (355 mL)**

Flat Label





Top Ply



Top Ply (Page #1)

Drug Facts (continued)

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 (1-800-222-1222) right away.

Directions

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Back of Top Ply (Page #2)

Bottom Ply

dose 30 mL (2 TBSP) to adults and children 12 years and older 60 mL (4 TBSP) 15 mL (1 TBSP) to children 6 to 11 years 30 mL (2 TBSP) children under 6 years ask a doctor Other information ■ each tablespoon (15 mL) contains: calcium 20 mg and magnesium 495 mg
■ store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F) and avoid freezing. Close cap tightly after use. *Inactive ingredients* flavor, purified water, saccharin sodium Questions or comments? © 1-855-274-4122 * This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Phillips'® Milk of Magnesia. PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC, MATTHEWS, NC 28105 your*plus*guarantee. 1-800-432-6111 or harristeeter.com

> Base (Page #3)

MILK OF MAGNESIA

magnesium hydroxide liquid

Product Information				
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:72036-005	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	1200 mg in 15 mL	

Inactive Ingredients				
Ingredient Name	Strength			
PEPPERMINT (UNII: V95R5KMY2B)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				

Product Characteristics			
Color	WHITE (White to off-white)	Score	
Shape		Size	

Flavor	PEPPERMINT		Imprint Code		
Contains					
Packaging					
# Item Code	Package Descrip	tion Ma	arketing Start Date	Marketing En	d Date
1 NDC:72036-005-16	355 mL in 1 BOTTLE; Type 0: Not a	Combination Product 01/2	ict 01/28/2016		
Maybeting Information					
Marketing Information					
Marketing Categ	gory Application Number or	Monograph Citation M	Marketing Start Date	Marketing En	d Date
OTC MONOGRAPH NO	OTC MONOGRAPH NOT FINAL part334		1/28/2016		

Labeler - Harris Teeter (047279351)

Registrant - Aurohealth LLC (078728447)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aurohealth LLC		078728447	MANUFACTURE(72036-005)	

Revised: 12/2019 Harris Teeter