

MILK OF MAGNESIA - magnesium hydroxide liquid
Aurohealth 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.

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 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 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 535 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

purified water

Questions or comments?

1-855-274-4122

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

Distributed by:

Aurohealth LLC.
2572 Brunswick Pike
Lawrenceville, NJ 08648

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

AUROHEALTH
NDC 58602-322-16

*Compare to the active ingredient in Phillips'® Milk of Magnesia

Milk of Magnesia

Saline Laxative

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

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

TAMPER-EVIDENT: Do not use if imprinted neckband is missing or broken.

12 FL OZ

(355 mL)

Original Flavor

Flat Label

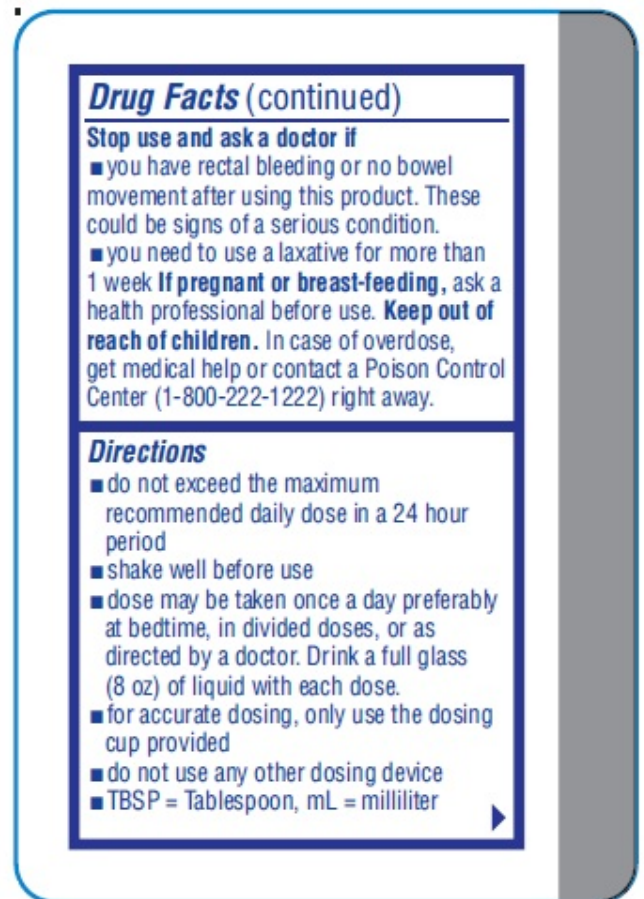




Top Ply



Top Ply
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Bottom Ply

Drug Facts (continued)	
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Base (Page #3)

MILK OF MAGNESIA

magnesium hydroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-322
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)	

Product Characteristics

Color	WHITE (White to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-322-16	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2016	09/01/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	01/28/2016	09/01/2022

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(58602-322)

Revised: 11/2020

Aurohealth LLC