MILK OF MAGNESIA- magnesium hydroxide suspension Publix Super Markets Inc

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.

Publix Super Markets, Inc. 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 and magnesium 595 mg
- does not meet USP requirements for preservative effectiveness
- store at 68° - 77° F (20° - 25° C)
- close cap tightly after use
- avoid freezing

Inactive ingredient

purified water

Package/Label Principal Display Panel

milk of magnesia

MAGNESIUM HYDROXIDE, 1200 mg/15 mL

SALINE LAXATIVE

comfortable, cramp-free relief

gentle, dependable

overnight relief

sugar free

stimulant free

ORIGINAL FLAVOR

Compare to the active ingredient in Phillips' $^{\circledR}$ Milk of Magnesia

12 FL OZ (355 mL)



NDC 56062-727-40

milkofmagnesia

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: 39640 63 F&

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Inactive ingredient purified water

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

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MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:56062-727

Route of Administration ORAL

Active Ingredient/Active Moiety

0	.		
	Ingredient Name	Basis of Strength	Strength
MAGNESIUM HYDRO XIDE (UNII: N HYDRO XIDE ION - UNII:9 159 UV38 1	IBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838,	MAGNESIUM HYDRO XIDE	1200 mg in 15 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			

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

	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 ND	C:56062-727-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/08/2019	

Labeler - Publix Super Markets Inc (006922009)

Revised: 4/2019 Publix Super Markets Inc