

## **MILK OF MAGNESIA- magnesium hydroxide suspension**

**VistaPharm, 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.*

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### **Milk of Magnesia**

saline laxative/antacid

### **DESCRIPTION**

Active Ingredient

(in each 5 mL = 1 teaspoonful)

Magnesium Hydroxide.....400 mg

### **Inactive Ingredients**

anhydrous citric acid, benzyl alcohol, methylparaben, propylene glycol, propylparaben, purified water.

### **FOR USE AS A LAXATIVE**

### **INDICATIONS**

#### **Uses**

- For relief of occasional constipation (irregularity)
- This product generally produces bowel movement in 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 more than 2 weeks

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

- presently 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**

- **shake well before use**

- drink a full glass (8 oz) of liquid with each dose
- mL = milliliter

Adults and children 12 years of age and older	30 mL to 60 mL
Children 6 to 11 years of age	15 mL to 30 mL
Children under 6 years of age	Consult a physician.

or as directed by a physician.

- The dose may be taken as a single daily dose or in divided doses.

## FOR USE AS AN ANTACID

### INDICATIONS

#### Uses

For the relief of

- heartburn
- sour stomach
- acid indigestion
- and upset stomach associated with these symptoms

### WARNINGS

**Do not take** more than 12 teaspoonfuls in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a physician

#### May have laxative effect

#### Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

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

- presently taking a prescription drug. Antacids may interact with certain prescription drugs.

**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

- **shake well before use**
- mL = milliliter
- adults and children 12 years old and older, take 1 to 3 teaspoonfuls (5 to 15 mL) four times a day or as directed by a physician
- do not take more than 12 teaspoonfuls (60 mL) in 24-hour period
- do not use the maximum dosage for more than 2 weeks
- children under 12 years: consult a physician

## **KEEP OUT OF REACH OF CHILDREN**

**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.

## **HOW SUPPLIED**

Milk of Magnesia USP 400 mg/5 mL is a white opaque liquid supplied as follows:

NDC 66689-053-01: 30 mL unit-dose cup

NCD 66689-053-99: Case contains 100 unit-dose cups of 30 mL (NDC 66689-053-01), packaged in 10 trays of 10 unit-dose cups each.

## **STORAGE**

### **Other Information**

- Protect from freezing
- Store at 20° to 25°C (68° to 77°F)

### **Questions or Comments?**

**Call 1-888-655-1505 (toll-free)**

Distributed by:

**VistaPharm, Inc.**

Largo, FL 33771, USA

VP2152R1

09/17

## **PRINCIPAL DISPLAY PANEL - 30 mL Cup Label**

### **Milk of Magnesia, USP**

2,400 mg Magnesium Hydroxide per 30 mL

### **Delivers 30 mL**

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F).

### **Shake Well**

### **XACTDOSE™**

Manufactured by:

VistaPharm, Inc.

Largo, FL 33771, USA

VP2153R2

01/18

NDC 66689-053-01

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 ACT DOSE™  
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VP2153 R2  
01/18



NDC 66689-053-01

## MILK OF MAGNESIA

magnesium hydroxide suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66689-053
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	400 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

WATER (UNII: 059QF0KO0R)

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66689-053-99	10 in 1 CASE	04/19/2018	
1		10 in 1 TRAY		
1		30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	04/19/2018	

**Labeler** - VistaPharm, Inc. (116743084)

Revised: 11/2020

VistaPharm, Inc.