

## **MAGNESIUM HYDROXIDE- magnesium hydroxide liquid**

**Rebel Distributors Corp**

*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 Drug Facts**

#### **Active ingredient**

Magnesium Hydroxide 400mg

#### **Purpose**

Saline Laxative / Antacid

#### **Keep Out of Reach of Children**

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Uses**

**Laxative:** relieves occasional constipation; generally produces a bowel movement in 1/2 to 6 hours.

**Antacid:** relieves heartburn, sour stomach & acid indigestion.

#### **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 2 weeks

**Ask a doctor or pharmacist before use** if you are taking any other drug.

° antacids may interact with certain prescription drugs ° laxatives may affect how other drugs work, so should be taken 2 or more hours before or after other drugs.

**When using this product** as an antacid, it may have a laxative effect.

**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 ° symptoms last more than 2 weeks.

**If pregnant or breast-feeding,** ask a health professional before use.

#### **Other Information**

each 5 mL teaspoon contains: magnesium 165mg and sodium 2 mg

store at room temperature

protect from freezing

keep tightly closed

#### **Directions**

**Laxative:** ° shake well before using

° drink a full glass (8 ounces) of liquid with each dose

° may be taken as a single or divided dose

**Antacid:** ° do not take more than 12 teaspoons in 24 hours

° do not use maximum dosage for more than 2 weeks

**Laxative:**

adults and children 12 years and older: 2 to 4 tablespoons

children 6 to under 12 years: 1 to 2 tablespoons

children 2 to under 6 years: 1 to 3 teaspoons

children under 2 years: ask a doctor

**Antacid:**

adults and children 12 years and older: 1 to 3 teaspoons with water, up to 4 times daily

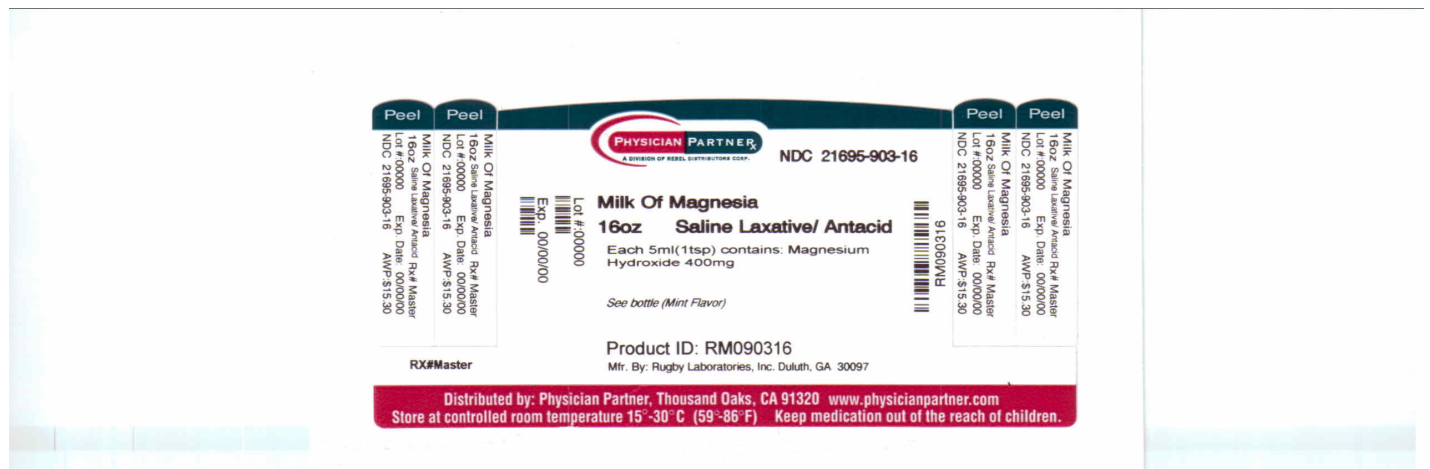
children under 12 years: ask a doctor

**Inactive ingredients**

flavor, purified water, saccharin sodium, sodium hypochlorite

**Questions or comments?** Call 1-800-645-2158, 9 am - 5 pm EST, Monday-Friday

**Package/Label Principal Display Panel**



<b>MAGNESIUM HYDROXIDE</b>			
magnesium hydroxide liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21695-903(NDC:0536-2470)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

<b>MAGNESIUM HYDRO XIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM HYDRO XIDE - UNII:NBZ3QY004S)	MAGNESIUM HYDRO XIDE	400 mg in 5 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM HYPOCHLORITE</b> (UNII: DY38VHM5OD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-903-16	473 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	03/22/2010	

**Labeler** - Rebel Distributors Corp (118802834)

### Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp