MILK OF MAGNESIA - magnesium hydroxide suspension Physicians Total Care, 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.

Drug Facts

Active Ingredients

Magnesium hydroxide 1200 mg

Purpose

Saline laxative

Uses

- relieves occasional constipation (irregularity)
- usually 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 over 14 days

Ask a doctor or pharmacist before use if you are

taking any other drug. Take this product 2 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 this and all drugs out of the reach of children

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

Directions

- shake well before use
- do not exceed the maximum recommended daily dose in a 24 hour period
- dose may be taken once a day, in divided doses, or as directed by a doctor

• drink a full glass (8oz) of liquid with each dose

adults and children 12 years 2 to 4 tabletspoonfuls

and older

(TBSP)

children 6 to 11 years

1 to 2 tablespoonfuls

(TBSP)

children under 6 years

ask a doctor

Other information

- each 15 mL tables poonful contains: magnesium 500 mg
- store at room temperature and avoid freezing
- close cap tightly after use
- TAMPER-EVIDENT: Do not use if imprinted neckband is missing or broken.

Inactive Ingredients

flavor, purified water, saccharin sodium, sodium hypochlorite

Principal Display Panel

Compare to Active Ingredient in Phillips Milk of Magnesia

Rugby Milk of Magnesia is distributed by Rugby Laboratories, Inc. Duluth, GA 30097

Additional barcode labeling by; Physicians Total Care, Inc. Tulsa, Oklahoma 74146

Milk of Magnesia

Magnesium Hydroxide 1200mg Saline Laxative Mint Flavor

Net Contents 16 fl oz (473 mL)



MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54868-2345(NDC:0536-2470)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM HYDRO XIDE UNII:NBZ3QY004S)

MAGNESIUM
HYDRO XIDE
in 15 mL

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
SODIUM HYPOCHLORITE (UNII: DY38 VHM5OD)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-2345-0	473 mL in 1 BOTTLE, PLASTIC		
2	NDC:54868-2345-2	355 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part334	06/19/1997	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 1/2012 Physicians Total Care, Inc.