CAREONE MILK OF MAGNESIA- magnesium hydroxide liquid American Sales Company

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.

American Sales Company Milk of Magnesia Drug Facts

Active ingredient (in each 15 mL TBSP)

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

shake well before use

- do not exceed the maximum recommended daily dose in a 24 hour period
- 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
- TBSP = tablespoonful

adults and children 12 years and older	2 to 4 TBSP.
children 6 to 11 years	1 to 2 TBSP.
children under 6 years	ask a doctor

Other information

- each tablespoon (15 mL) contains: calcium 20 mg, magnesium 595 mg, potassium 2 mg and sodium 2 mg
- does not meet USP requirements for preservative effectiveness
- store at 20-25°C (68-77°F)
- keep tightly closed

Inactive ingredients

anhydrous citric acid, D&C red #28, flavor, glycerin, purified water, sorbitol solution, sucrose, xanthan gum

Principal Display Panel

Compare to the Active Ingredient in Phillips'® Milk of Magnesia

MILK OF MAGNESIA

Saline Laxative / Magnesium Hydroxide

WILD CHERRY FLAVOR

ALCOHOL 0.4%

Dependable Overnight Relief

Comfortable, Cramp Free Relief

Stimulant Free

Compare to the Active Ingredient in Phillips'® Milk of Magnesia*

CAREONE®

Saline Laxative / Magnesium Hydroxide



WILD CHERRY FLAVOR

ALCOHOL 0.4%

- Dependable Overnight Relief
- · Comfortable, Cramp Free Relief
- · Stimulant Free

:94940 D4 F2

12 FL OZ (355 ml)

Drug Facts

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

Active ingredient (in each 15 mL TBSP)

Purpose

Magnesium hydroxide 1200 mg......Saline laxative

- Uses relieves occasional constipation (irregularity)
- 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 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)

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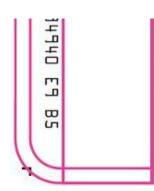
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(Questions or comments? 1-800-719-9260



distributor of Phillips'® Milk of Magnesia.

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017 CIN 3611142 www.myleader.com 1-800-200-6313



CAREONE MILK OF MAGNESIA

magnesium hydroxide liquid

Product Information

Product Type HUMAN OTC DRUG LABEL

Item Code (Source)

NDC:41520-949

Route of Administration

ORAL

DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

MAGNESIUM HYDRO XIDE (MAGNESIUM CATION and HYDRO XIDE ION)

MAGNESIUM HYDRO XIDE

1200 mg in 15 mL

Inactive Ingredients

inactive ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID		
GLYCERIN		
WATER		
SORBITOL		
SUCROSE		
XANTHAN GUM		
D&C RED NO. 28		

Product Characteristics

Color	PINK (Opaque Light pink)	Score
Shape		Size
Flavor	CHERRY (wild cherry)	Imprint Code
Contains		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-949-40	355 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/26/2012	

Labeler - American Sales Company (809183973)

Revised: 1/2013 American Sales Company