

LEADER MILK OF MAGNESIA- magnesium hydroxide suspension
Cardinal Health 110, LLC. dba Leader

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.

Cardinal Health 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, magnesium 595 mg, and sodium 2 mg
- does not meet USP requirements for preservative effectiveness
- store at 20-25°C (68-77°F)
- close cap tightly after use
- avoid freezing

Inactive ingredients

light mineral oil, peppermint oil, purified water, saccharin sodium

Questions or comments?

1-800-719-9260

Principal Display Panel

Genuine

Milk of Magnesia

Magnesium Hydroxide, 1200 mg per 15 mL

Saline Laxative

COMPARE TO PHILLIPS'® MILK OF MAGNESIA active ingredient

Fresh Mint Flavor

Sugar-Free

Stimulant-Free

Cramp-Free

100% Money Back Guarantee

12 FL OZ (355 mL)

LEADERTM

NDC 70000-0483-1

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12 FL OZ (355 mL)

: 33240 E9 F10

Drug Facts DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

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33240 EQ 810

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

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
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100% Money Back Guarantee
Return to place of purchase if not satisfied.

CIN 5503412 REV. 1/19



LEADER MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0483 |
| 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 | 1200 mg in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|--|
| Color | WHITE (opaque) | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|------------------------------|--|---|----------------------|--------------------|
| 1 | NDC:70000-0483-1 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/20/2019 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part334 | 02/20/2019 | | |

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader