

MILK OF MAGNESIA ORIGINAL- magnesium hydroxide liquid
American Health Packaging

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.

Original Flavor Milk of Magnesia
(Magnesium Hydroxide)
Saline Laxative
8442972/0820F

Active ingredient (in each 30 mL cup)

Magnesium hydroxide 2400 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 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 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 preferably at bedtime, in divided doses, or as directed by a doctor
- drink a full glass (8 oz) of liquid with each dose

| | |
|--|---|
| adults and children 12 years and older | 1 unit dose cup (30 mL) to 2 unit dose cups (60 mL) |
| children 6 to 11 years | ½ unit dose cup (15 mL) to 1 unit dose cup (30 mL) |
| children under 6 years | ask a doctor |

Other information

- **each 30 mL cup contains:** magnesium 1000 mg
- store at room temperature and avoid freezing
- **DO NOT USE IF SEAL IS BROKEN**
- This drug product is supplied in 30 ml unit dose cups as:
100 cups (10 x 10) ND 60687-429-76

Inactive ingredients

purified water, sodium hypochlorite

PACKAGING INFORMATION

American Health Packaging unit dose cups (see Other Information section) contain drug product from Geri-Care Pharmaceuticals as follows:
(2400 mg per 30 mL / 100 UD) NDC 60687-429-76 packaged from NDC 57896-649

Distributed by:

American Health Packaging
Columbus, OH 43217

8442972/0920F

Principal Display Panel – Tray

**Original Flavor
Milk of Magnesia
(Magnesium Hydroxide)
Saline Laxative**

FOR INSTITUTIONAL USE ONLY

**Store at room temperature
and avoid freezing.**

8442972/0920F

Original Flavor

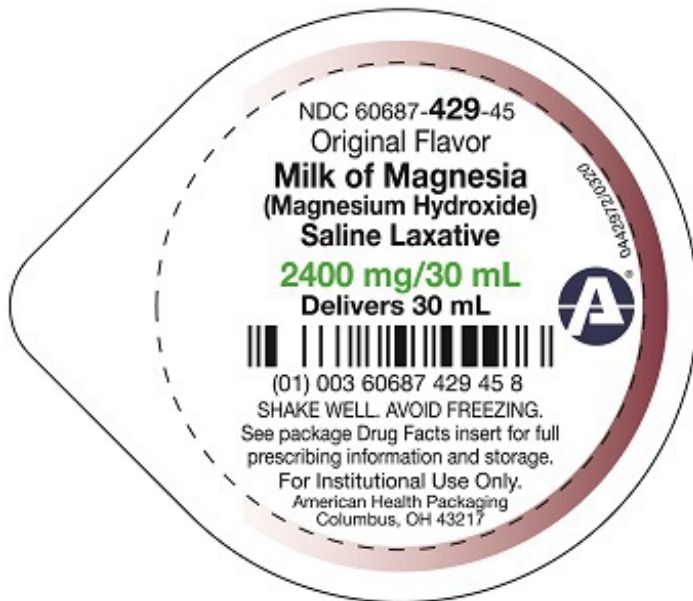
**Milk of Magnesia
(Magnesium Hydroxide)
Saline Laxative**

FOR INSTITUTIONAL USE ONLY

**Store at room temperature
and avoid freezing.**

8442972/0920F

Principal Display Panel – Cup



NDC 60687- 429-45

**Original Flavor
Milk of Magnesia
(Magnesium Hydroxide)
Saline Laxative**

**2400 mg/30 mL
Delivers 30 mL**

SHAKE WELL. AVOID FREEZING.

See package Drug Facts insert for full
prescribing information and storage.

For Institutional Use Only

American Health Packaging
Columbus, OH 43217

0442972/0320

MILK OF MAGNESIA ORIGINAL

magnesium hydroxide liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:60687-429(NDC:57896-649)

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 |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM HYPOCHLORITE (UNII: DY38VHM5OD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:60687-429-76 | 10 in 1 CASE | 09/01/2020 | |
| 1 | NDC:60687-429-51 | 10 in 1 TRAY | | |
| 1 | NDC:60687-429-45 | 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 not final | part334 | 09/01/2020 | |

Labeler - American Health Packaging (929561009)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|---------------------|
| American Health Packaging | | 929561009 | repack(60687-429) |

Revised: 8/2020

American Health Packaging