

MILK OF MAGNESIA CHERRY- magnesium hydroxide liquid
Chain Drug Marketing Association

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.

qc mom cherry

Active ingredient (in each 15 mL tablespoonful)

Magnesium hydroxide 1200 mg

Purpose

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 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 failure to have a 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
- follow each dosage with a full glass (8 oz) of liquid

| | |
|-----|------|
| age | dose |
|-----|------|

| | |
|---------------------------------------|-----------------------|
| adults and children 12 years and over | 2 to 4 tablespoonfuls |
| children 6 to 11 years | 1 to 2 tablespoonfuls |
| children under 6 years | ask a doctor |

Other information

- each 15 mL tablespoonful contains: magnesium 500 mg, sodium 6 mg
- store at room temperature and avoid freezing
- close cap tightly after use

Inactive ingredients

carboxymethylcellulose sodium, citric acid, D and C red no. 28, flavor, glycerin, microcrystalline cellulose, purified water, sodium citrate, sodium hypochlorite, sucrose, xanthan gum.

package Label

Drug Facts TAMPER EVIDENT: Do not use if imprinted neckband is missing or broken.

| | |
|--|-----------------|
| Active ingredient (in each 15 mL tablespoonful) | Purpose |
| Magnesium hydroxide 1200 mg | Saline laxative |

Use

- relieves occasional constipation (irregularity)
- generally produces bowel movement in ½ to 6 hours

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MILK OF MAGNESIA CHERRY

magnesium hydroxide liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-310 |
| 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 |
|--|----------|
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| D&C RED NO. 28 (UNII: 767IP0Y5NH) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SODIUM HYPOCHLORITE (UNII: DY38VHM5OD) | |
| SUCROSE (UNII: C151H8M554) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|----------|--------------------------|--------------|--|
| Color | pink (opaque light pink) | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63868-310-12 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/01/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 04/01/2014 | |

Labeler - Chain Drug Marketing Association (011920774)

Registrant - GCP Laboratories (965480861)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|----------------|---------------|----------------------------|
| GCP Laboratories | | 965480861 | manufacture(63868-310) |

Revised: 12/2018

Chain Drug Marketing Association