MILK OF MAGNESIA- magnesium hydroxide liquid Rij Pharmaceutical Corporation

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 Ingredient (in each 5 mL) One teaspoonful)

Magnesium Hydroxide 400 mg

Purpose

Saline laxative/Antacid

Use

Laxative

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

Antacid

• relieves acid indigestion, sour stomach, heartburn.

Warnings

Ask a doctor before use if you have

- kidney disease
- stomach pain, nausea or vomiting
- notice a sudden change in bowel habits that persists over a period of 2 weeks
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Antacid may interact with certain prescription drugs.

When using this product

- it may have a laxative effect
- do not exceed the maximum recommended daily dosgae in a 24-hour period

Stop use and ask a doctor if

Laxative

- you have rectal bleeding or failure to have a bowel movement after use. These may indicate a serious condition.
- you need to use a laxative for more than one week

Antacid

• symptoms last for more than 2 weeks.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

• shake well before use

| | Laxative use: | Antacid use |
|---|--|--|
| | Do not use dosage cup for ages under 12 years. Follow each dose with a full glass (8 oz) of liquid. | Do not use dosage cup. Follow each dose with a little water. |
| adults and children 12 years and older | 2-4 TBSP (30-60 mL) once a day | 1-3 tsp (5-15 mL) up to 4 times a day |
| 6 to 11 years | 1-2 TBSP (15-30 mL) once a day | ask a doctor |
| 2 to 5 years | 1-3 tsp (5-15 mL) once a day | ask a doctor |
| under 2 years | ask a doctor | ask a doctor |

Other information

- TAMPER EVIDENT: Do not use if breakaway band on cap is broken or missing.
- Store at room temperature 15° 30°C (59° 86°F)
- keep tightly closed
- keep from freezing
- each teaspoon (5 mL) contains: magnesium 166 mg
- each teaspoon (5 mL) contains: sodium 1 mg

Inactive ingredients

citric acid, flavor, purified water, sodium hypochlorite.

Principal Display Panel



MILV OF MACNESIA

| WILL OF WIAGNESIA | | | | | | |
|---------------------------------|-----------------|--------------------|----------------------|----------|--|--|
| magnesium hydroxide liquid | | | | | | |
| | | | | | | |
| Product Information | | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:5380 | 7-401 | | |
| Route of Administration | ORAL | | | | | |
| | | | | | | |
| Active Ingredient/Active Moiety | | | | | | |
| fictive ingreatent/fictive info | | | Desta of | | | |
| | Ingredient Name | | Basis of Strength | Strength | | |
| | | | | | | |

| MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII: T6 V3LHY838, HYDRO XIDE ION - UNII: 9159 UV381P)MAGNESIUM CATION - UNII: T6 V3LHY838, HYDRO XIDE ION - UNII: 9159 UV381P) | | | | | | 400 mg in 5 mL | |
|---|----------------------|---|--------------|-------------------|--------|-------------------|----------|
| | | | | | | | |
| Inactive Ingredie | ents | | | | | | |
| | | Ingredient Name | | | | Stre | ngth |
| CITRIC ACID MONO | HYDRA | FE (UNII: 2968PHW8QP) | | | | | |
| WATER (UNII: 059QF0KO0R) | | | | | | | |
| SODIUM HYPOCHLC | ORITE (U | JNII: DY38 VHM50D) | | | | | |
| | | | | | | | |
| Product Charact | eristic | S | | | | | |
| Color | WHITE (opaque) Score | | | | | | |
| Shape | hape Size | | | | | | |
| Flavor | | PEPPERMINT | Imprint Code | | | | |
| Contains | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | | Package Description | | Marketing Start D | Date 1 | Marketing | End Date |
| | | in 1 BOTTLE; Type 0: Not a Combination Produc | | 03/16/1999 | | | |
| 2 NDC:53807-401-16 | 473 mL | in 1 BOTTLE; Type 0: Not a Combination Produc | ct | 03/16/1999 | | | |
| | | | | | | | |
| | | | | | | | |
| Marketing Inf | forma | ition | | | | | |
| Marketing Catego | ory A | Application Number or Monograph Citation | n | Marketing Start D | ate | Marketing | End Date |
| OTC monograph not fi | inal pa | rt334 | | 03/16/1999 | | | |
| | | | | | | | |

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|----------------------------|
| Rij Pharmaceutical Corporation | | 144679156 | manufacture(53807-401) |

Revised: 4/2018

Rij Pharmaceutical Corporation