

MILK OF MAGNESIA ORIGINAL - magnesium hydroxide liquid
TYA Pharmaceuticals

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.

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

• kidney disease • a magnesium-restricted diet • stomach pain, nausea, or vomiting • a sudden change in bowel habits that lasts over 14 days taking a prescription drug. This product may interact with certain prescription drugs. • 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 ask a health professional before use.

Ask a doctor before use if you have

Ask a doctor or pharmacist before use if you are

Stop use and ask a doctor if

If pregnant or breast-feeding,

In case of overdose, get medical help or contact a Poison Control Center right away. **Keep out of reach of children.**

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: 2 to 4 tablespoonfuls children 6 to 11 years: 1 to 2 tablespoonfuls children under 6 years: ask a doctor

Other information

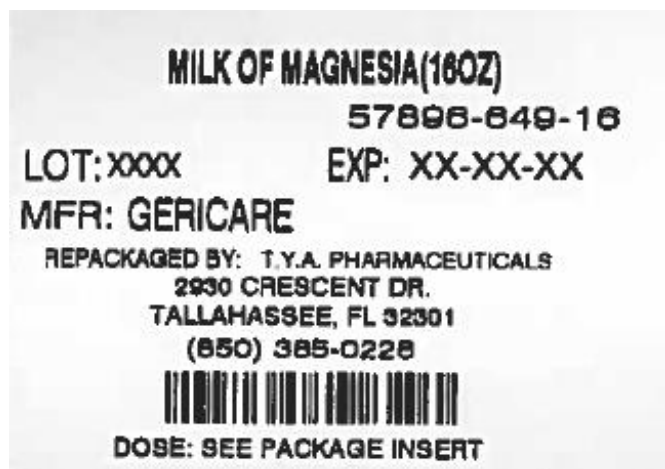
• magnesium 500 mg • store at room temperature and avoid freezing • close cap tightly after use • **each 15 mL tablespoonful contains:**

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

Inactive ingredients

purified water, sodium hypochlorite

MILK OF MAGNESIA ORIGINAL (MAGNESIUM HYDROXIDE) LIQUID



MILK OF MAGNESIA ORIGINAL

magnesium hydroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64725-0649(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)	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:64725-0649-1	16 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2000	

Labeler - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment

Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-0649) , REPACK(64725-0649)

Revised: 5/2012

TYA Pharmaceuticals