MILK OF MAGNESIA- magnesium hydroxide suspension McKesson Corporation dba SKY Packaging

Milk of Magnesia

Active ingredient(s)

Magnesium hydroxide 400mL

Purpose

Saline laxative

Use(s)

As an antacid

- heartburn
- upset/sour stomach
- acid indigestion

As a Laxative (usually within 1/2 to 6 hours)

• occasional constipation (irregularity)

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

Pregnancy/Breastfeeding 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

As an Antacid

- do not exceed the maximum recommended daily dose in a 24 hour period
- shake well before use
- can be taken with water
- mL = milliliter

adults and children 12 years of age and over 5 to 15 mL (1 to 3 teaspoonfuls) children under 12 years of age ask a doctor

Laxative

- do not exceed the maximum recommended daily dose of 60 mL 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.
- mL = milliliter; TBSP = Tablespoon

Other information

- each teaspoonful (5 mL) contains: magnesium 400 mg
- store at room temperature, 20° 25°C (68° 77°F). Avoid freezing.
- Milk of Magnesia USP (white suspension, spearmint flavor) is supplied in the following oral dosage form:

NDC 63739- 30 mL unit dose cup. Case contains 100 unit dose cups of 30 mL 196-10: packaged in 10 trays of 10 unit dose cups each.

Inactive ingredients

flavoring, hydroxypropyl methylcellulose, methylparaben, potassium citrate, propylene glycol, propylparaben, purified water, antifoam af emulsion, sodium saccharin, and sorbitol.

Questions

Call 1-800-845-8210

MANUFACTURED BY Pharmaceutical Associates, Inc. Greenville, SC 29605

PRINCIPAL DISPLAY PANEL - 30 mL Cup Tray Label

NDC 63739-196-10

Milk of Magnesia USP ANTACID, SALINE LAXATIVE

Each 30 mL contains:

Magnesium Hydroxide 2400 mg

SHAKE WELL

USUAL DOSAGE: See attached Drug Facts

Package Not Child-Resistant

DISTRIBUTED BY

SKY Packaging

Memphis, TN 38141



F0431C300923

MILK OF MAGNESIA

magnesium hydroxide suspension

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Prod	UCT	ıntorr	nation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63739-196
I I O G G C C I V D C	TION IN CITE DINGS	itelli code (Sodice)	1100.00733 13

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MAGNESIUM HYDROXIDE (UNII: NBZ 3QY004S) (MAGNESIUM CATION - UNII: T6V3LHY838, HYDROXIDE ION - UNII: 9159UV381P) MAGNESIUM HYDROXIDE ION - UNII: 9159UV381P) HYDROXIDE in 5 mL

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POTASSIUM CITRATE (UNII: EE90ONI6FF)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
CYCLOMETHICONE 4 (UNII: CZ227117JE)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				
SORBITOL (UNII: 506T60A25R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739- 196-10	10 in 1 CASE	01/29/2024	
1		10 in 1 TRAY		
1	NDC:63739- 196-01	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

Labeler - McKesson Corporation dba SKY Packaging (140529962)

Registrant - PAI Holdings, LLC dba Pharmaceutical Associates, Inc. (044940096)

Establishment			
Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		044940096	analysis (63739-196), label(63739-196), manufacture(63739-196), pack(63739-196)

Revised: 2/2024 McKesson Corporation dba SKY Packaging