

ALUMINUM HYDROXIDE - aluminum hydroxide gel
LLC Federal Solutions

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 5 mL teaspoonful)

Aluminum hydroxide 320 mg

Purpose

Antacid

Uses

For the relief of

- heartburn
- acid indigestion
- sour stomach

Warnings

Ask a doctor or pharmacist before use if you are taking a prescription drug.

Antacids may interact with certain prescription drugs.

When using this product you may get constipated

Stop use and ask a doctor if symptoms last more than 2 weeks

Keep this and all drugs out of reach of children.

Directions

- shake well before using
- do not take more than 12 teaspoonfuls in 24 hours
- do not use the maximum dosage for more than 2 weeks
- **dosage:** 2 teaspoonfuls 5-6 times daily after meals and at bedtime followed by a sip of water if needed

Other information

- store at room temperature
- protect from freezing
- keep tightly closed

Inactive ingredients

benzyl alcohol, butylparaben, flavor, glycerin, hydroxyethylcellulose, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol solution

Questions or comments?

Call 1-855-333-6337

Repackaged by:

Safecor Health LLC

317 New Boston St.

Woburn, MA 01801

Distributed by:

LLC Federal Solutions

14 NE 1st Ave.

Miami, FL 33123

PRINCIPAL DISPLAY PANEL

NDC: 24451-091-30
ALUMINUM HYDROXIDE
GEL, USP
1920 mg / 30 mL
DELIVERS 30 mL
SUGAR FREE
MINT FLAVOR
SHAKE WELL BEFORE USING
Exp: 00/00/00 Lot # 00000

Rpk By: Safecor Health LLC
Woburn, MA 01801
Dist. By: LLC Federal Solutions
Miami, FL 33132



ALUMINUM HYDROXIDE

aluminum hydroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24451-091(NDC:0536-0091)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	320 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1I1U3FV8)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (MINT FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24451-091-30	100 in 1 BOX		
1		30 mL in 1 CUP, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	08/12/2013	

Labeler - LLC Federal Solutions (965036895)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	repack(24451-091)

Revised: 8/2013

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