ANTACID- aluminum hydroxide, magnesium hydroxide and simethicone suspension Safeway

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.

Maximum Strength Antacid Liquid

Active ingredient (in each 5mL tsp.)

Aluminum hydroxide (equvi. to dried gel, USP) 400 mg

Magnesium hydroxide 400 mg

Simethicone 40 mg

Purpose

Antacid

Antacid

Antigas

Uses

- relieves:
- acid indigestion
- heartburn
- sour stomach
- upset stomach and gas associated with these symptoms

Warnings

Do not take more than 8 teaspoonfuls in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are

• presently taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor

if symptoms last more than two weeks

Keep out of reach of children.

Directions

- shake well before use.
- adults and children 12 years and older: take 2 to 4 teaspoonfuls two times a day, or as directed by a
 doctor

• children under 12 years: consult a doctor

Other information

- each teaspoon contains: magnesium 170 mg, sodium 5 mg
- store at controlled room temperature 20°C-25°C (68°F-77°F)
- do not freeze

Inactive ingredients

flavor, glycerin, hydroxyethylcellulose, methylparaben, propylene glycol, purified water, saccharin sodium, simethicone emulsion, sorbitol

PDP

Compare to Maalox maximum strength liquid cherry active ingredients

Maximum strength

Antacid Liquid

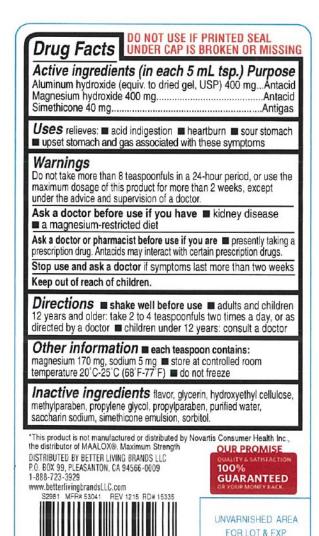
Aluminum Hydroxide 400 mg - Antacid

Magnesium Hydroxide 400 mg - Antacid

Simethicone 40 mg - Antigas







(LINE DOES NOT PRINT)

ANTACID

aluminum hydroxide, magnesium hydroxide and simethicone suspension

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-508 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	400 mg in 5 mL	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838)	MAGNESIUM HYDRO XIDE	400 mg in 5 mL	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	40 mg in 5 mL	

Ina	ctive Ingredients	
	Ingredient Name	Strength

GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

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

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:21130-508-05	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/12/20 15	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	12/12/2015	

Labeler - Safeway (009137209)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	manufacture(21130-508)	

Revised: 1/2016 Safeway