ANTACID- aluminum hydroxide, magnesium hydroxide and simethicone suspension CVS

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.

CVS 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 the active ingredients in Maalox max Maximum strength Antacid Liquid Antacid / Anti-gas Fast relief of: Heartburn Acid indigestion Pressure & Bloating Cherry Flavor 12 FL OZ (355 mL)



ANTACID								
aluminum hydroxide, magnesium hydroxide and simethicone suspension								
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Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:69842-508				
Route of Administration	ORAL							
Active Ingredient/Active Moiety								
Ingredient Name				rength	Strength			
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)			ALUMINUM HYDRO XIDE		400 mg in 5 mL			
MAGNESIUM HYDRO XIDE (UNII: NBZ UNII:T6 V3LHY8 38)	MAGNESIUM HYDRO XIDE		400 mg in 5 mL					
DIMETHICONE (UNII: 92RU3N3Y1O) (1	DIMETHICONE		40 mg in 5 mL					

40 mg in 5 mL

DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)

Inactive Ingredients							
		Ingredient Name			S	Strength	
GLYCERIN (UNII: PDC6.	A3C0OX)						
HYDRO XYETHYL CELL	LULOSE (1	00 MPA.S AT 2%) (UNII: R33S	7TK2EP)				
METHYLPARABEN (UN	II: A2I8C7HI	9T)					
PROPYLPARABEN (UN	II: Z8IX2SC1	IOH)					
WATER (UNII: 059QF0K	(O0R)						
SACCHARIN SODIUM (UNII: SB8ZU	JX40TY)					
SORBITOL (UNII: 506T	60A25R)						
Product Characteristics							
Color		white	Score				
Shape			Size				
Flavor		CHERRY	Imprint Code				
Contains							
Packaging							
# Item Code		Package Description	Marketing Start Date	Marketin	g End Date		
1 NDC:69842-508-05 355 mL in 1 BOTTLE; Type 0: Not a Combination Product 03/09/2011							
Marketing Information							
Marketing Category	arketing Category Application Number or Monograph Citation			Marketing Start Date Marketi		g End Date	
OTC monograph final	part332		03/09/2011				

Labeler - CVS (062312574)

Establishment								
Name	Address	ID/FEI	Business Operations					
Guardian Drug Company		119210276	manufacture(69842-508)					

Revised: 8/2017