ANTACID - aluminum hydroxide, magnesium hydroxide, simethicone liquid H E B

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.

HEB Antacid

ACTIVE INGREDIENT (in each 10 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 400 mg Magnesium hydroxide 400 mg Simethicone 40 mg

PURPOSE

Antacid Antacid Antigas

USE(S)

relieves:

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

WARNINGS

Do not take more than 80 mL 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 DOCTOR

KEEP OUT OF REACH OF CHILDREN

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DIRECTIONS

- shake well before use
- mL = milliliter
- adults and children 12 years and older: take 10 mL to 20 mL four times a day, or as directed by a doctor
- children under 12 years: consult a doctor

OTHER INFORMATION

- each 10 mL contains: magnesium 170 mg, sodium 5 mg
- store at controlled room temperature 20°C-25°C (68°-77°F)
- do not freeze

INACTIVE INGREDIENTS

ethyl alcohol, flavor, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol

PRINCIPAL DISPLAY PANEL

NDC 37808-554-05

HEB

Antacid

Aluminum hydroxide, 400 mg Magnesium hydroxide, 400 mg Simethicone, 40 mg

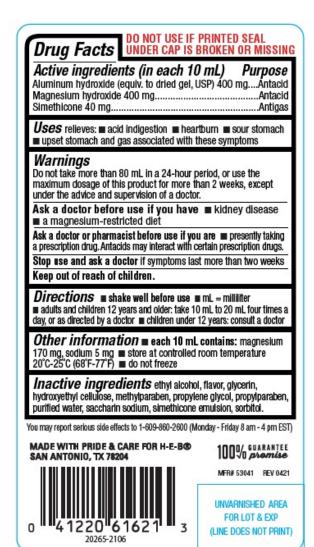
Antacid & Antigas

Relief of:

- Heartburn
- Acid Indigestion
- Sour Stomach
- Pressure & Bloating

Original Flavored Liquid





ANTACID

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-554 Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	400 mg in 10 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	400 mg in 10 mL
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	40 mg in 10 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)		
METHYLPARABEN (UNII: A218C7HI9T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

1	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:37808-554- 05	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/13/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	12/13/2021	

Labeler - H E B (007924756)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(37808-554)	

Revised: 12/2021 H E B