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 5 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 200 mg Magnesium hydroxide 200 mg Simethicone 20 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

if symptoms last more than two weeks

KEEP OUT OF REACH OF CHILDREN

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• shake well before use

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

OTHER INFORMATION

- each 5 mL contains: magnesium 85 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

Compare to Mylanta® Regular Strength active ingredients* NDC 37808-138-05

HEB

Antacid Aluminum hydroxide, 200 mg Magnesium hydroxide, 200 mg Simethicone, 20 mg

Antacid & Antigas

Relief of:

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

Original Flavored Liquid

12 FL OZ (355 mL) Alcohol content 0.2% v/v



ANTACID									
aluminum hydroxide, magnesium hydroxide, simethicone liquid									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source) NI		NDC:378(DC:37808-138				
Route of Administration	ORAL								
Active Ingredient/Active Moi	ety								
Ingredient Name			Basis of Strength		Strength				
ALUMINUM HYDRO XIDE (UNII: 5QB0 UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE		200 mg in 5 mL						
MAGNESIUM HYDRO XIDE (UNII: NBZ3Q Y004S) (MAGNESIUM CATION - UNII:T6 V3LHY838)			MAGNES IUM HYDRO XIDE		200 mg in 5 mL				
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)			DIMETHICONE		20 mg in 5 mL				

Inactive Ingredients								
		Ingredient Nar	ne		S	trength		
ALCOHOL (UNII: 3K9958V90M)								
GLYCERIN (UNII: PDC6A3C0OX)								
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)								
METHYLPARABEN (UNII: A2I8C7HI9T)								
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)								
PROPYLPARABEN (UNII: Z8IX2SC10H)								
WATER (UNII: 059QF0KO0R)								
SACCHARIN SODIUM (UN		(40TY)						
SORBITOL (UNII: 506T60	A25R)							
Product Characteristics								
Color		WHITE	Score					
Shape	ape Size							
Flavor	avor Imprint Code							
Contains								
Packaging								
# Item Code		Package Description	Marketing Start Date	Marketing	End Date			
1 NDC:37808-138-05 355 mL in 1 BOTTLE; Type 0: Not a Combination Product				10/08/2018				
Marketing Information								
Marketing Category	Applica	cation Number or Monograph Citation		Marketing Start Date	Marketing End Date			
OTC MONOGRAPH FINAL	part331			10/08/2018				

Labeler - HEB (007924756)

Establishment							
Name	Address	ID/FEI	Business Operations				
Guardian Drug Company		119210276	MANUFACTURE(37808-138)				

Revised: 10/2018