ANTACID ANTIGAS - aluminum hydroxide, magnesium hydroxide, simethicone liquid Retail Business Services, LLC.

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.

Careone Regular Strength Antacid Antigas Liquid

ACTIVE INGREDIENTS (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

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 10 mL 20 mL four times a day, or as directed by a doctor
- children under 12 years: consult a doctor
- mL = milliliter

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

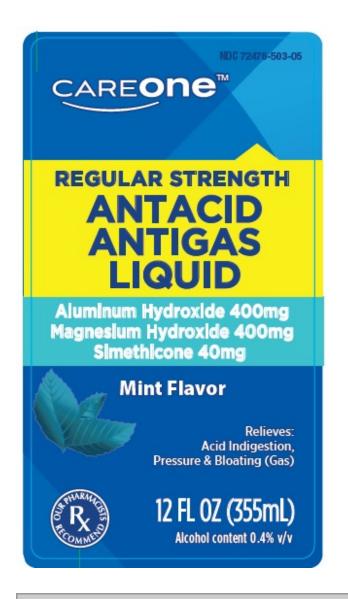
Careone NDC 72476-503-05

REGULAR STRENGTH
ANTACID ANTIGAS LIQUID

Aluminum Hydroxide 400mg
Magnesium Hydroxide 400mg
Simethicone 40mg
Mint Flavor

Relieves:

Acid Indigestion, Pressure & Bloating (Gas)





ANTACID ANTIGAS

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-503
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 (2000 MPA.S AT 1%) (UNII: S38J6RZ N16)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-503- 05	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	05/26/2021	

Labeler - Retail Business Services, LLC. (967989935)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(72476-503)	

Revised: 5/2021 Retail Business Services, LLC.