

**ANTACID - 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

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**
- 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 72476-509-05

CAREONE

REGULAR STRENGTH

ANTACID LIQUID

Aluminum hydroxide 400 mg
Magnesium hydroxide 400 mg
Simethicone 40 mg

Original Flavor

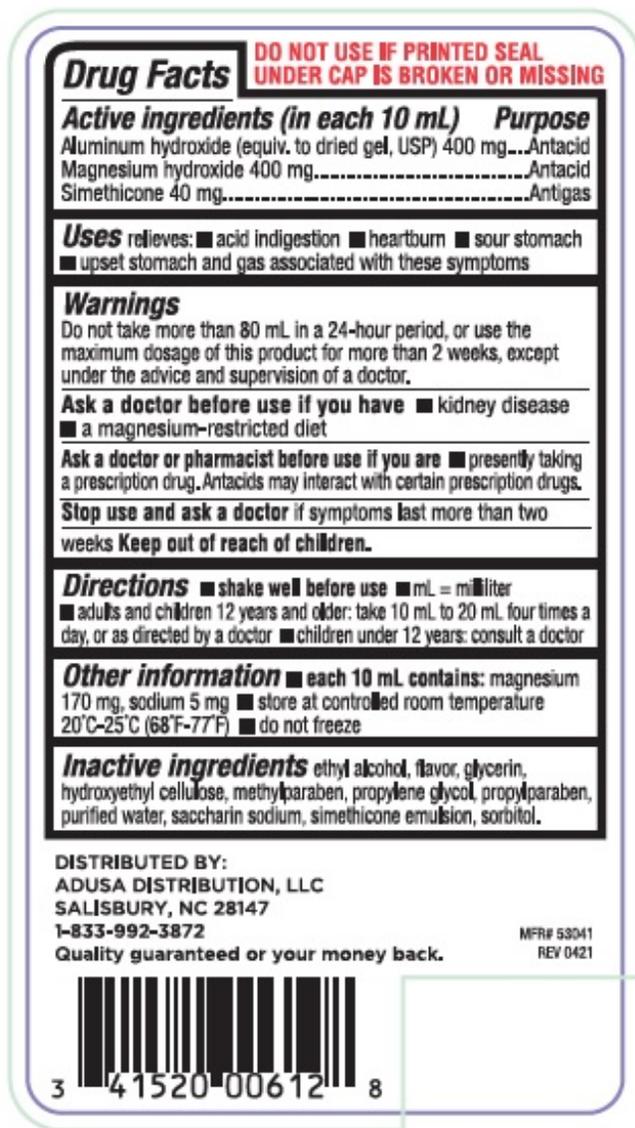
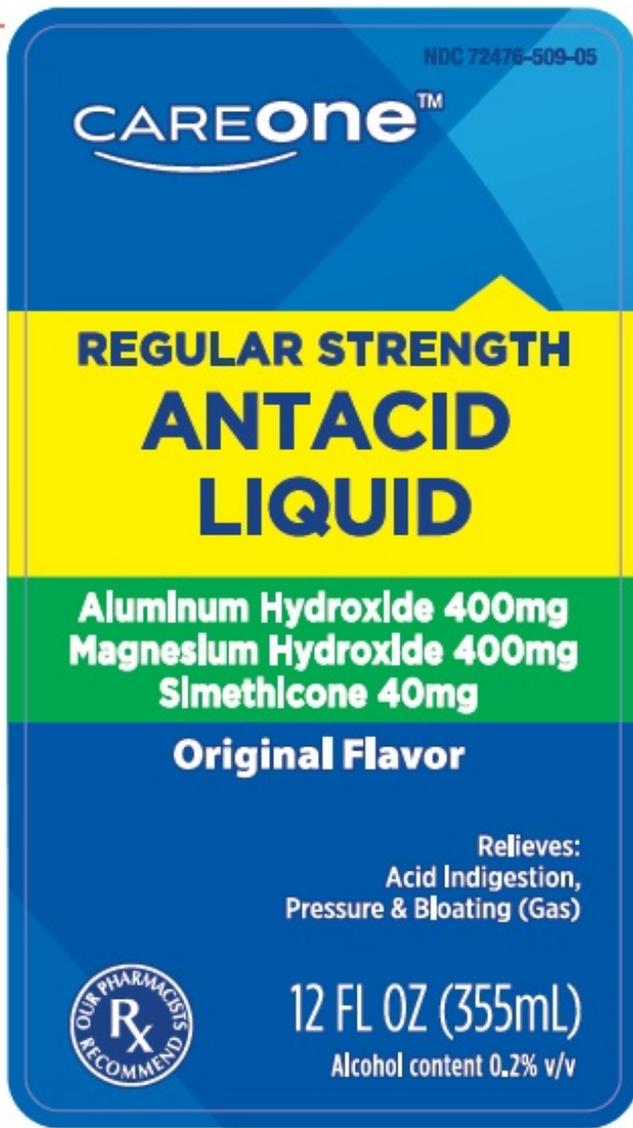
Relieves:

Acid Indigestion,

Pressure & Bloating (Gas)

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)	NDC:72476-509
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 -	MAGNESIUM	400 mg

UNII:T6V3LHY838)	HYDROXIDE	in 10 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	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: S38J6RZN16)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
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:72476-509-05	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	10/21/2021	

Labeler - Retail Business Services, LLC. (967989935)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(72476-509)

Revised: 10/2021

Retail Business Services, LLC.