MAXIMUM STRENGTH ANTACID MINT - aluminum hydroxide, magnesium hydroxide, simethicone liquid
Topco Associates, 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.

Topco Maximum Strength Antacid Mint

ACTIVE INGREDIENTS (in each 10 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 800 mg
Magnesium hydroxide 800 mg
Simethicone 80 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 60 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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DIRECTIONS

- **shake well before use**
- 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
- mL = milliliter

OTHER INFORMATION

- **each 10 mL contains:** magnesium 340 mg, sodium 5 mg
- store at controlled room temperature 20ºC-25ºC (68º-77ºF)
- 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

Topcare Health

COMPARE TO MYLANTA® MAXIMUM STRENTH ACTIVE INGREDIENTS*

NDC 36800-342-40

MAXIMUM STRENGTH

Antacid

Advanced

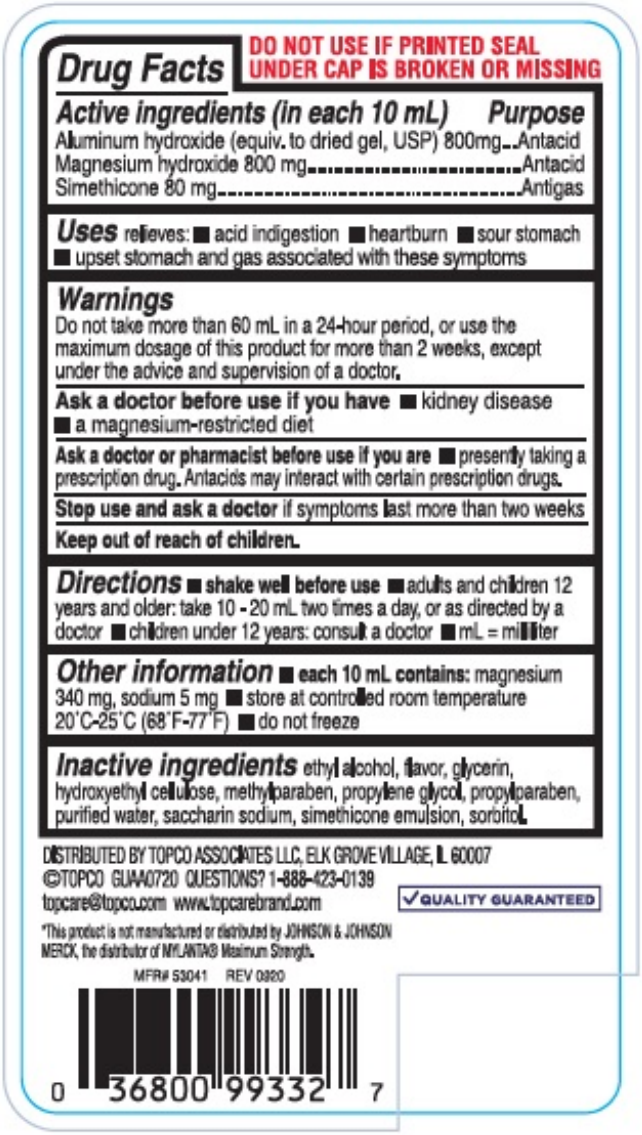
ANTACID & ANTIGAS

FAST RELIEF

- Heartburn
- Acid Indigestion
- Pressure
- Bloating (Gas)

ALCOHOL 0.2% v/v

MINT FLAVOR
12 FL OZ (355 mL)



MAXIMUM STRENGTH ANTACID MINT

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-342
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	800 mg in 10 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	800 mg in 10 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
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	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-342-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	09/01/2020	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations

Guardian Drug Company		119210276	MANUFACTURE(36800-342)