MAXIMUM STRENGTH ANTACID CHERRY LIQUID - 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 Cherry liquid

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 20°C-25°C (68°-77°F)
- do not freeze

INACTIVE INGREDIENTS

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

PRINCIPAL DISPLAY PANEL

Topcare health NDC 36800-587-40

MAXIMUM STRENGTH
Antacid

Advanced

ANTACID & ANTIGAS

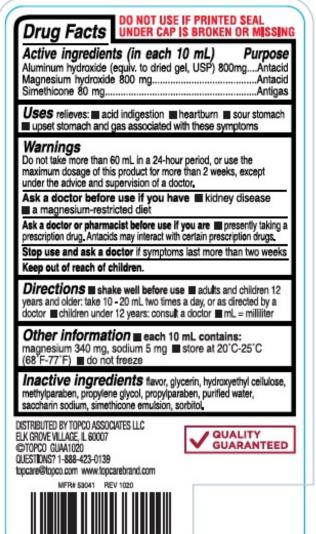
FAST RELIEF

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

12 FL OZ (355 mL)

CHERRY FLAVOR





MAXIMUM STRENGTH ANTACID CHERRY LIQUID

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-587 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:50B0T2IUN0)	ALUMINUM HYDROXIDE	800 mg in 10 mL	

MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	800 mg in 10 mL
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	80 mg in 10 mL

Inactive Ingredients			
Ingredient Name	Strength		
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	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N 4		355 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	10/01/2020	

Labeler - Topco Associates, LLC (006935977)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(36800-587)	

Revised: 2/2021 Topco Associates, LLC