

**REGULAR 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.*

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**Topco Regular Strength Antacid Mint**

**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 to 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 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**

Topcare Health  
NDC 36800-582-40

## **REGULAR STRENGTH**

**Antacid**

**Advanced**

## **ANTACID & ANTIGAS**

## **FAST RELIEF**

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

**ALCOHOL 0.4% v/v**

**12 FL OZ (355 mL)**  
**MINT FLAVOR**



NDC 36800-582-40

**REGULAR STRENGTH**

# Antacid

## Advanced

ANTACID & ANTIGAS

FAST RELIEF



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



Scan here for more information or call 1-888-423-0139

ALCOHOL 0.4% v/v

**12 FL OZ**  
**(355 mL)**



**MINT FLAVOR**

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

**Drug Facts**

Active ingredients (in each 10 mL)	Purpose
Aluminum hydroxide (equiv. to dried gel, USP) 400 mg	Antacid
Magnesium hydroxide 400 mg	Antacid
Simethicone 40 mg	Antigas

**Uses** 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 a 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 - 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 20°C-25°C (68°F-77°F) ■ do not freeze

**Inactive ingredients** ethyl alcohol, flavor, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol.

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 topcare@topco.com www.topcarebrand.com

QUALITY GUARANTEED

MFR# 53041 REV 1020



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## REGULAR STRENGTH ANTACID MINT

aluminum hydroxide, magnesium hydroxide, simethicone liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-582
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	400 mg in 10 mL
<b>MAGNESIUM HYDROXIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	400 mg in 10 mL
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	40 mg in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-582-40	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**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Guardian Drug Company		119210276	MANUFACTURE(36800-582)

Revised: 10/2020

Topco Associates, LLC