ANTACID- aluminum hydroxide, magnesium hydroxide, simethicone suspension Shopko Stores Operating Co., 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.

Shopko Antacid Drug Facts

Active ingredients (in each 10 mL)

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

Purposes

Antacid

Antigas

Uses

relieves

- heartburn
- acid indigestion
- sour stomach
- upset stomach due to these symptoms
- pressure and bloating commonly referred to as gas

Warnings

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.

When using this product

do not exceed 60 mL in a 24-hour period, or use the maximum dosage for more than 2 weeks

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

shake well before use

- measure with dosing cup provided
- **adults and children 12 years and over:** 10 mL 20 mL between meals, at bedtime or as directed by a doctor
- do not take more than 60 mL in any 24 hour period
- do not use the maximum dosage for more than 2 weeks
- children under 12 years: ask a doctor
- mL = milliliter

Other information

- each 10 mL contains: magnesium 350 mg, potassium 20 mg and sodium 3 mg
- does not meet USP requirements for preservative effectiveness
- store at $20-25^{\circ}$ C (68-77°F), do not freeze

Inactive ingredients

butylparaben, flavor, hypromellose, microcrystalline cellulose and carboxymethylcellulose sodium, potassium citrate, propylparaben, purified water, simethicone emulsion, sorbitol, sorbitol solution

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare To Maximum Strength Mylanta® active ingredients

MAXIMUM STRENGTH

ANTACID

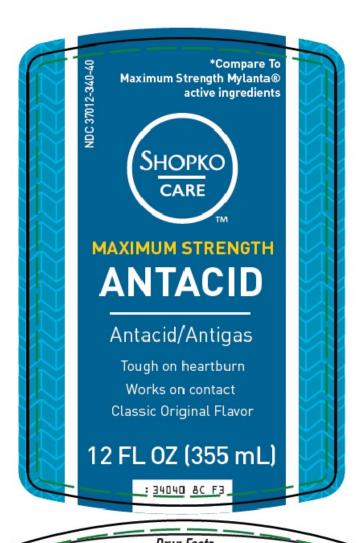
Antacid/Antigas

Tough on heartburn

Works on contact

Classic Original Flavor

12 FL OZ (355 mL)





Drug Facts Active ingredients (in each 10 mL) Purposes Aluminum hydroxide (equiv. to dried gel, USP) 800 mg. ..Antacid Magnesium hydroxide 800 mg...... Simethicone 80 mg...... ...Antigas Uses relieves ■ heartburn ■ acid indigestion ■ sour stomach ■ upset stomach due to these symptoms pressure and bloating commonly referred to as gas **Warnings** 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. When using this product do not exceed 60 mL in a 24-hour period, or use the maximum dosage for more than 2 weeks Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Directions ■ shake well before use ■ measure with dosing cup provided ■ adults and children 12 years and over: 10 mL - 20 mL between meals, at bedtime or as directed by a doctor ■ do not take more than 60 mL in any 24 hour period do not use the maximum dosage for more than 2 weeks ■ children under 12 years: ask a doctor ■ mL = milliliter Other information ■ each 10 mL contains: magnesium 350 mg, potassium 20 mg and sodium 3 mg ■ does not meet USP requirements for preservative effectiveness ■ store at 20-25°C (68-77°F), do not freeze Inactive ingredients butylparaben, flavor, hypromellose,

microcrystalline cellulose and carboxymethylcellulose sodium, potassium citrate, propylparaben, purified water, simethicone emulsion, sorbitol, sorbitol solution

Drug Facts

(continued)

Questions or

comments?

1-800-719-9260

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ANTACID

aluminum hydroxide, magnesium hydroxide, simethicone suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-340
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	800 mg in 10 mL	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	800 mg in 10 mL	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg in 10 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)		
POTASSIUM CITRATE (UNII: EE90ONI6FF)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	WHITE (opaque)	Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:37012-340-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/05/2013	

Labeler - Shopko Stores Operating Co., LLC (023252638)

Revised: 12/2019 Shopko Stores Operating Co., LLC