MAALOX ANTACID - aluminum hydroxide, magnesium hydroxide, simethicone liquid Physicians Total Care, Inc.

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.

Active ingredient (in each 5 mL teaspoon)

Aluminum hydroxide (equiv. to dried gel, USP) 200 mg

Magnesium hydroxide 200 mg

Simethicone 20 mg

Purpose

Antacid

Antigas

Uses

for the relief of

- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with 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

now taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product

do not exceed 16 teaspoonsful (80 mL) in a 24-hour period or use the maximum dosage for more than 2 weeks unless directed by a doctor

Keep out of reach of children.

Directions

- shake well before using
- adults and children 12 years and older: take 2-4 tsp (10-20 mL) up to 4 times a day or as directed by a doctor
- children under 12: ask a doctor

Other information

- each teaspoon contains: calcium 25 mg and magnesium 85 mg
- store at 20°-25°C (68°-77°F)
- does not meet USP requirements for preservative effectiveness

Inactive ingredients

butylparaben, carboxymethylcellulose sodium, flavor, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol

Questions or comments?

1-800-719-9260

Principal Display Panel

Regular Strength

Liquid Antacid

Antacid & Anti-Gas

Fast Relief of:

Heartburn

Acid Indigestion

Sour Stomach & Upset Stomach

Mint Flavor

Maalox Antacid 12 fl oz (355 mL)

NDC 54868-2093-0



Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-2093(NDC:0113-0851)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0 T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0 T2IUN0)	ALUMINUM HYDRO XIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3Q Y004S) (MAGNESIUM HYDRO XIDE - UNII:NBZ3Q Y004S)	MAGNES IUM HYDRO XIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients					
Ingredient Name	Strength				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)					
BUTYLPARABEN (UNII: 3QPI1U3FV8)					
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)					
HYPROMELLOSES (UNII: 3NXW29V3WO)					
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)					
PROPYLPARABEN (UNII: Z8IX2SC10H)					
WATER (UNII: 059QF0KO0R)					
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)					
SORBITOL (UNII: 506T60A25R)					

ColorWHITE (opaque)ScoreShapeSize	
Shape Size	
Flavor MINT Imprint Code	
Contains	

Packaging						
#	Item Code	Package Description	Marketin	g Start Date	Μ	arketing End Date
1	NDC:54868-2093-0	355 mL in 1 BOTTLE				
Marketing Information						
N	Marketing Category	Application Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date
0	TC monograph final p	art332		12/12/2006		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment					
Name	Address	ID/FEI	Business Operations		
Physicians Total Care, Inc.		194123980	relabel		

Revised: 1/2012

Physicians Total Care, Inc.