MELOX- aluminum hydroxide, magnesium hydroxide, simethicone suspension Belmora 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.

Melox

Drug Facts

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200 mg (equivalent to dried gel USP)

Magnesium hydroxide 200 mg

Simethicone 20 mg

Purpose

Antacid

Antigas

Uses

relieves • acid indigestion • heartburn • sour stomach • the symptoms referred to as gas

Warnings

Ask a doctor before use if you have

• kidney disease • magnesium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than 2 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Directions

- shake well before each use
- adults and children 12 years and older: take 2 to 4 teaspoonfuls between meals, at bedtime, or as directed by a doctor
- do not exceed 16 teaspoonfuls in a 24 hour period or use the maximum dosage for more than 2 weeks
- children under 12: ask a doctor

Other information

• each 5 mL teaspoonful contains: magnesium 85 mg, sodium 3 mg

- store at room temperature
- protect from freezing
- keep tightly closed

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

Questions or comments?

1-888-779-2877

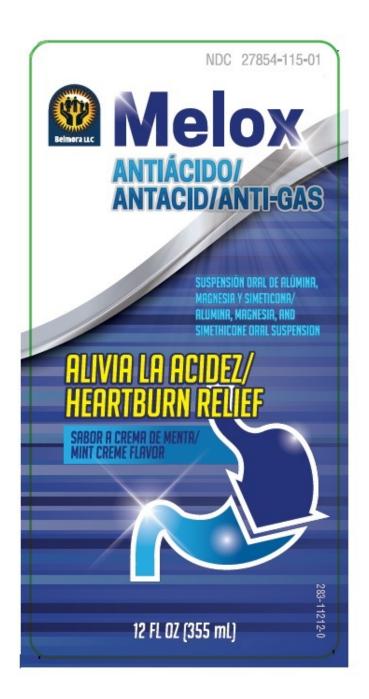
HEARTBURN RELIEF

TAMPER EVIDENT: Do not use if breakaway band on cap is broken or missing.

 $\hbox{$\mathbb{D}* This product is not manufactured or distributed by the owner of the registered trademark $Maalox^{\circledR}$}$

Distributed by: Belmora LLC, 2231 Crystal Dr.#1000, Arlington, VA 22202 www.melox.com

Packaging



Levantar aqui para español

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983-11212-0



MELOX

aluminum hydroxide, magnesium hydroxide, simethicone suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:27854-115

Route of Administration ORAL

Active Ingredient/Active Moiety

8 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3			
Ingredient Name	Basis of Strength	Strength	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	200 mg in 5 mL	
MAGNESIUM HYDRO XIDE (UNII: NBZ3Q Y004S) (MAGNESIUM CATION - UNII:T6 V3LHY838)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics	roduct Characteristics			
Color		Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

ı	Packaging							
ı	# Item Co	ode Package Descrip	ption Marketing Start Date M	Marketing End Date				
ı	1 NDC:27854-	115-01 355 mL in 1 BOTTLE; Type 0: Not a	Combination Product 06/01/2018					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part331	06/01/2018			

Labeler - Belmora LLC (112753244)

Revised: 11/2018 Belmora LLC