MELOX- aluminum hydroxide, magnesium hydroxide, simethicone liquid 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 10 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 400 mg Magnesium hydroxide 400 mg Simethicone 40 mg

Purpose

Antacid Antacid 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

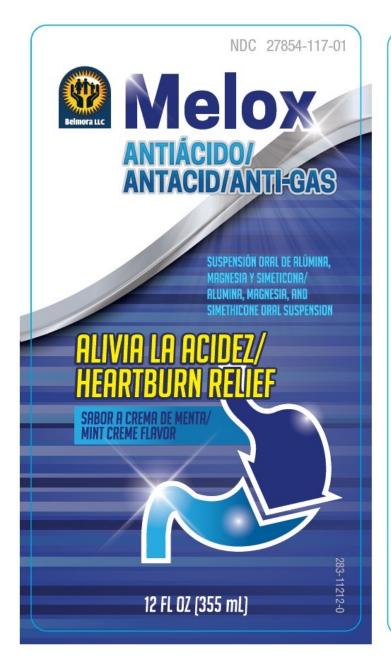
ethyl alcohol, flavor, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol.

Belmora LLC

ALUMINA, MAGNESIA, AND SIMETHICONE ORAL SUSPENSION
HEARTBURN RELIEF
MINT CREME FLAVOR

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

Packaging



Drug Facts DO NOT USE IF PRINTED S UNDER CAP IS BROKEN OF HITCOME

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MELOX

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:27854-117

Route of Administration ORAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	400 mg in 10 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	400 mg in 10 mL

DIMETHICONE	(UNII: 92RU3N3Y10) (DIMETHICONE -	UNII:92RU3N3Y10)
DIFFERENCE V	(OIVII. 32NOSNSTIO	/ (DIMETHICONE -	ONII. 32NOSNOTEO)

DIMETHICONE

40 mg in 10 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)		
METHYLPARABEN (UNII: A218C7H19T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL (UNII: 506T60A25R)		

l	P	Packaging Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:27854-117- 01	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	05/01/2023	

Labeler - Belmora LLC (112753244)

Revised: 5/2023 Belmora LLC