MI-ACID REGULAR STRENGTH - aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Central Texas Community Health Centers

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.

Mi-Acid Regular Strength

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200 mg (equivalent to dried gel, USP)

Magnesium hydroxide 200 mg

Simethicone 20mg

Purposes

Antacid

Antigas

Uses

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms 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 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 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 take more than 24 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks

• children under 12 years: ask a doctor

Other information

- each 5 mL teaspoonful contains: magnesium 85 mg, sodium 1 mg
- store at room temperature
- protect from freezing
- keep tightly closed
- TAMPER-EVIDENT: Do not use if breakaway band on bottle is missing or broken.

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL - 355 ML Bottle Label

CommUnityCare Federally Qualified Health Centers

MI-ACID

ALT

MAALOX

R.S.

355ML

Date:

Name:

Dr.

USE AS DIRECTED. (Alternative for Maalox R.S.)

123456

1/1/01

MI-ACID REG. STRENGTH 355ML NDC 76413-319-01

Batch: 123456 Lot: 123456 Exp: 1/1/01 MAJOR

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

CommUnityCare Federally Qualified Health Centers

MI-ACID ALT MAALOX R.S.

Date:

355ML Name:

Dr.

USE AS DIRECTED. (Alternative for Maalox R.S.)

USAR COMO INDICADO. (Alternativa para Maalox R.S.)

123456

1/1/01 MI-ACID REG. STRENGTH 355ML NDC 76413-319-01

Batch: 123456 Lot: 123456 Exp: 1/1/01 MAJOR

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

MI-ACID REGULAR STRENGTH

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-319(NDC:0904-0004)	
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	200 mg in 5 mL	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)			
BUTYLPARABEN (UNII: 3QPI1U3FV8)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
PROPYLPARABEN (UNII: Z8 IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
SORBITOL (UNII: 506T60A25R)			

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

ı	Pa	ckaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:76413-319-01	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	02/01/2011	

Labeler - Central Texas Community Health Centers (079674019)

Establishment				
Name	Address	ID/FEI	Business Operations	
Central Texas Community Health Centers		079674019	REPACK(76413-319), RELABEL(76413-319)	

Revised: 4/2016 Central Texas Community Health Centers