

ADVANCED ANTACID REGULAR STRENGTH- aluminum hydroxide, magnesium hydroxide, dimethicone liquid
NuCare Pharmaceuticals, 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.

SUNMARK ANTACID ORIGINAL

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200mg (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

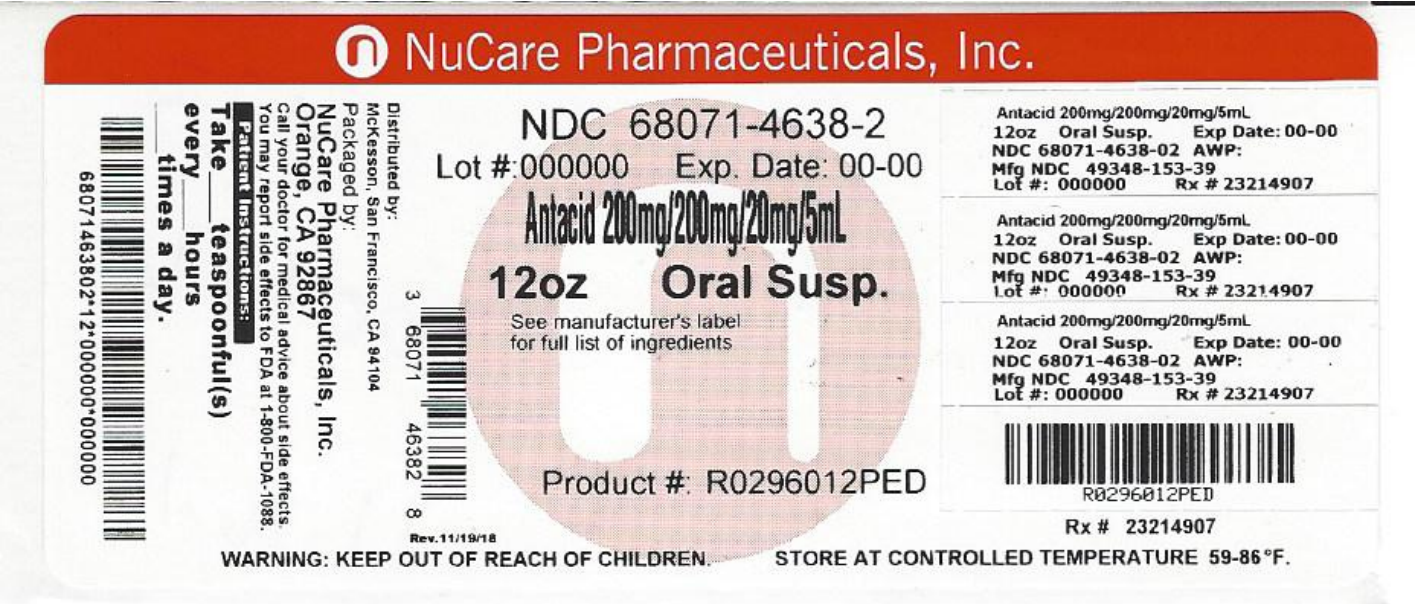
Other information

- **each 5 mL teaspoonful contains:** magnesium 85 mg, sodium 1 mg
- protect from freezing
- store at room temperature
- keep tightly closed

Inactive ingredients

benzyl alcohol, butylparaben, flavor (contains alcohol), hydroxyethylcellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

package label



ADVANCED ANTACID REGULAR STRENGTH			
aluminum hydroxide, magnesium hydroxide, dimethicone liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-4638(NDC:49348-153)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of	Strength

Ingredient Name	Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	200 mg in 5 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4638-2	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/01/2012	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4638)

Revised: 2/2021

NuCare Pharmaceuticals,Inc.