RELIEF OTC ANTACID- calcium carbonate, potassium bicarbonate, sodium bicarbonate liquid Tummy Company, 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.

Relief OTC Antacid

Active ingredients (in each 4 oz Dose)

Calcium carbonate USP 545mg
Potassium bicarbonate USP 905mg
Sodium bicarbonate USP 2110mg

Purpose

Antacid

Antacid

Antacid

Uses

for the relief of

• Heartburn • Acid Indigestion • Sour Stomach

Warnings

Ask a doctor before use if you have

- •Kidney Disease
- •A Potassium or Sodium-Restricted Diet

Ask a doctor or pharmacist before use if you

are currently taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop Use and ask a doctor

if you have taken the maximum dose for 2 weeks.

If pregnant or breastfeeding,

ask a health professional before use.

Keep this out of the reach of children.

Directions

- Do not use if outer seal is broken, replace cap tightly
- Do not exceed daily recommended dosage
- Shake well & drink 2-4 ounces as symptoms occur

Adults and children 12
years and over
Adults 60 and over
Children under 12 years

Up to 4oz. every 4 hours as sumptoms occur or as Do not exceed 16 ounces in 24 hours

Do not exceed 12 ounces in 24 hours

Ask a doctor

Ask a doctor

Other information

• Each 4 oz Dose contains: sodium 640mg

• Each 4 oz Dose contains: potassium 353mg

• Each 4 oz Dose contains: calcium 218mg

• Store below 86 degrees F (30 degrees C)

Inactive ingredients

magnesium hydroxide, metyl paraben, natural flavors, propyl paraben, purified water, sucralose

Questions or comments?

1-888-959-6207 weekdays

reliefotc.com

Representative Label

New!

Fast heartburn Relief

OTC

antacid

great tasting

ORANGE CREME

12 fl. oz. (354 mL)

Fast Heartburn Relief Begins with One Sip!

Heartburn Relief that's Easy to Swallow.

A Great Tasting, Non-Chalky, Clear Liquid

Take RELIEF OTC ANYTIME for

- Hearburn
- Acid Indigestion
- Upset Stomach
- GLUTEN-FREE
- ALUMINUM-FREE
- ASPIRIN-FREE

Distributed by

Tummy Company, Inc.

Phoenix,



RELIEF OTC ANTACID

calcium carbonate, potassium bicarbonate, sodium bicarbonate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69016-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	545 mg in 118 mL		
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (POTASSIUM CATION -	DOTACCII IM CATION	905 mg		

UNII:295O53K152)	FOTASSION CATION	in 118 mL	
SODIUM BICARBONATE (UNII: 8 MDF5V39QO) (SODIUM CATION - UNII:LYR4M0 NH37)	SODIUM BICARBONATE	2110 mg in 118 mL	

Inactive Ingredients			
Ingredient Name	Strength		
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
PROPYLPARABEN (UNII: Z8 IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	ORANGE (Orange Creme)	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69016-001-18	118 mL in 1 BOTTLE			
2	NDC:69016-001-54	354 mL in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	05/28/2014	

Labeler - Tummy Company, Inc. (079165926)

Establishment				
Name	Address	ID/FEI	Business Operations	
Alera Technologies Inc.		962055740	manufacture(69016-001)	

Revised: 5/2014 Tummy Company, Inc.