

TROPICAL PANNED- calcium carbonate, simethicone tablet, chewable
BestCo 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.

Calcium carbonate 750mg
Simethicone 80mg

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Simethicone 80 mg

Purpose

Antacid

Anti-gas

Uses for the relief of:

- Acid indigestion
- Heartburn
- Sour stomach
- Upset stomach associated with these symptoms
- Bloating, pressure, or stuffed feeling commonl referred to as gas

Warnings

Do not use if you've ever had an allergic reaction to this product or any of its ingredients

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

When using this product

- Do not take more than 5 chewable tablets in a 24 hour period
- Do not use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a physician.
- Constipation may occur.

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

Keep out of reach of children

Directions

- Adults and children 12 years and older: Fully chew then swallow 1 or 2 chewable tablets as symptoms occur, or as directed by a doctor.
- Children under 12 years: consult a doctor.
- Do not take more than 5 chewable tablets in a 24 hour period.

Other information

- each chewable tablet contains: calcium 330 mg
- store at room temperature. Avoid excessive heat above 40C (104F)
- Close cap tightly after use

Inactive ingredients

acacia, carmine, carnauba wax, citric acid, corn starch, corn syrup, FD&C Red #40 Aluminum Lake, flavors, hydrogenated coconut oil, hydrogenated vegetable oil, lecithin, maltodextrin, methyl paraben,

modified starch, potassium hydroxide, pregelatinized modified starch, propyl paraben, propylene glycol, shellac, sorbic acid, sorbitol, sugar, titanium dioxide, triacetin, water, white wax

Questions

1-800-986-0369



Label:528474 Date:8/19/2015 Time:09:49:23



TROPICAL PANNED

calcium carbonate, simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52642-225
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	750 mg
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics

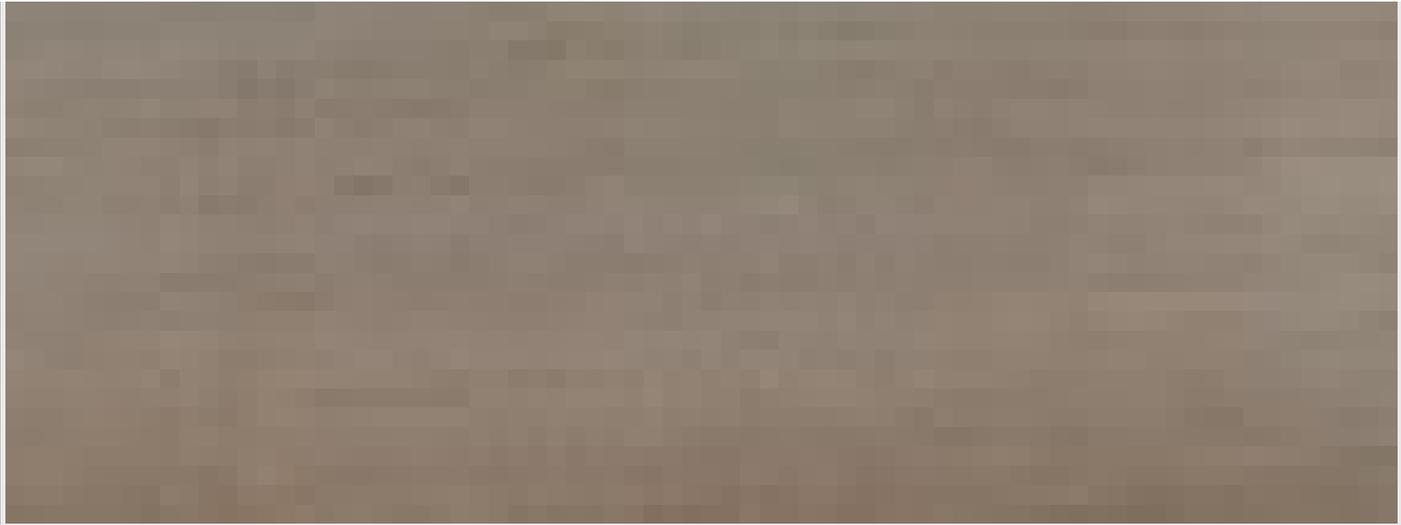
Color	yellow, orange, pink	Score	score with uneven pieces
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Shape	ROUND	Size	70mm
Flavor	LEMON, ORANGE, STRAWBERRY	Imprint Code	AS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52642-225-32	32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/19/2014	





Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	03/19/2014	

Labeler - BestCo Inc. (002149136)

Registrant - Bayer (112117283)

Establishment

Name	Address	ID/FEI	Business Operations
BestCo Inc.		002149136	manufacture(52642-225)

Revised: 2/2016

BestCo Inc.