

PHAZYME- simethicone and calcium carbonate tablet, chewable
C.B. Fleet 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.

Active Ingredients (in each chew)

Calcium carbonate 750mg..... Antacid

Simethicone 250mg..... Anti-gas

Uses for the relief of:

- pressure and bloating commonly referred to as gas
- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with these symptoms

When using this product

- do not take more than 2 chews 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 doctor

If pregnant or breast-feeding

Ask a doctor before use.

Ask a doctor or pharmacist before use if you are

Now taking a prescription drug. Antacids may interact with certain prescription drugs.

Keep out of reach of children

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Directions

Adults and children 12 years and older:

Chew and swallow 1 to 2 chews as symptoms occur or as directed by a doctor.

Other Information

- Each chew contains: calcium 300mg
- Store between 59-77F.
- Don't use if allergic to this product or its ingredients.

Inactive Ingredients

Acacia, beeswax, carnuba wax, citric acid, cornstarch, corn syrup, FD&C red #40 aluminum lake,

flavor, modified starch, phosphoric acid, polyvinylpyrrolidone, pregelatinized modified corn starch, propylene glycol, shellac, sodium benzoate, sorbic acid, sorbitol, soy lecithin, sucrose, titanium dioxide, vegetable oil, water

Questions?

1-855-727-4277 or www.phazyme.com

Principle Display Panel



PHAZYME

simethicone and calcium carbonate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0507
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	750 mg in 24
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	250 mg in 24

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
STARCH, CORN (UNII: O8232NY3SJ)	
CORN SYRUP (UNII: 9G5L16BK6N)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	12mm
Flavor	CHERRY	Imprint Code	PA
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0507-24	24 in 1 JAR; Type 0: Not a Combination Product	03/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	03/01/2016	

Labeler - C.B. Fleet Company, Inc. (003119054)

Revised: 10/2017

C.B. Fleet Company, Inc.