CALCIUM CARBONATE- calcium carbonate suspension
Pharmaceutical Associates, 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

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Calcium Carbonate 1250 mg
(Equivalent to 500 mg elemental Calcium)

Purpose

Antacid

Uses

Relieves:
- heartburn
- acid indigestion
- sour stomach
- upset stomach associated with these symptoms

Warnings

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

When using this product, do not take more than 6 teaspoonfuls (30 mL) in a 24-hour period or use the maximum dosage for more than 2 weeks.

Keep out of reach of children.

Directions
- **Shake well before using.**
- Take 1 to 2 teaspoonfuls (5 to 10 mL) as symptoms occur, or as directed by a doctor.

Other information
- store at 20° - 25°C (68° - 77°F)
- do not freeze
- Calcium Carbonate Oral Suspension is a pink-colored, bubble gum flavored suspension supplied in the following oral dosage forms:

NDC 0121-0766-16:	16 fl oz (473 mL) bottle
NDC 0121-4766-05:	5 mL unit dose cup. Case contains 40 unit dose cups of 5 mL packaged in 4 trays of 10 unit

dose cups each.

Inactive ingredients

calcium saccharin, citric acid, D&C Red No. 33, FD&C Red No. 40, flavoring, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sorbitol and xanthan gum.

Questions or comments?

Call 1-800-845-8210.

You may also report serious side effects to this phone number.

MANUFACTURED BY

Pharmaceutical
Associates, Inc.
Greenville, SC 29605

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0766-16

Quality ®
Value

Calcium Carbonate
Oral Suspension

1250 mg/5 mL

Maximum Strength
ANTACID

Daily source of calcium

SUGAR FREE / ALCOHOL FREE
SODIUM FREE

16 fl oz (473 mL)

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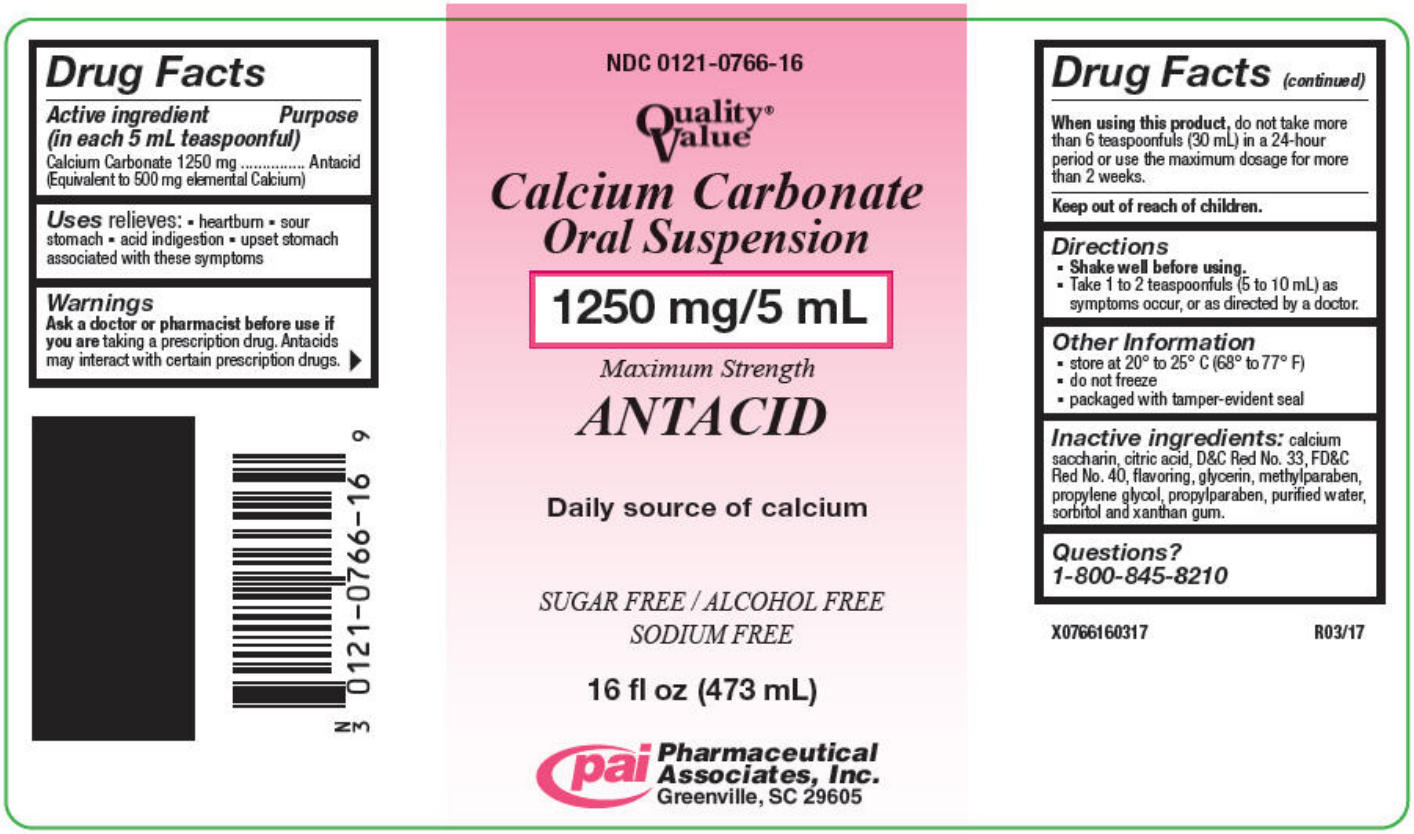

PRINCIPAL DISPLAY PANEL - 5 mL Cup Tray Label

NDC 0121-4766-05

Calcium Carbonate Oral
Suspension
Maximum Strength

1250 mg/5 mL
(equivalent to 500 mg of elemental Calcium)

SUGAR FREE/ ALCOHOL FREE/ SODIUM FREE

ANTACID – SHAKE WELL

USUAL DOSAGE: See attached Drug Facts

This unit-dose package is not child-resistant.

Store at 20° - 25°C (68° - 77°F)
10 x 5 mL Unit-Dose Cups

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T4766050218
R02/18

NDC 0121-4766-05

Calcium Carbonate Oral Suspension

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SUGAR FREE/ ALCOHOL FREE/ SODIUM FREE

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pai Pharmaceutical Associates, Inc.
Greenville, SC 29605

T4766050218 R02/18

Drug Facts

Active ingredient (in each 5 mL teaspoonful) — **Purpose**

Calcium Carbonate 1250 mg (Equivalent to 500 mg elemental Calcium) ..... Antacid

Uses

Relieves
- heartburn
- acid indigestion
- sour stomach
- upset stomach associated with these symptoms

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NDC 0121-0766-16: 16 fl oz (473 mL) bottle
NDC 0121-4766-05: 5 mL unit dose cup. Case contains 40 unit dose cups of 5 mL packaged in 4 trays of 10 unit dose cups each.

Inactive ingredients: calcium saccharin, citric acid, D&C Red No. 33, FD&C Red No. 40, flavoring, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sorbitol and xanthan gum.

Questions or comments? Call 1-800-845-8210.
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pai Pharmaceutical Associates, Inc.
Greenville, SC 29605
www.paipharma.com

R02/18

CALCIUM CARBONATE

calcium carbonate suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0766
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB, CARBONATE ION - UNII:7UJQ5OPE7D)	CALCIUM CARBONATE	1250 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SACCHARIN CALCIUM (UNII: 5101OP7P2I)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	pink	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0121-0766-16	12 in 1 CASE	12/01/2004	
1		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	12/01/2004	

CALCIUM CARBONATE

calcium carbonate suspension

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SACCHARIN CALCIUM (UNII: 5101OP7P2I)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	pink	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-4766-05	4 in 1 CASE	12/01/2004	
1		10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	12/01/2004	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations

Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0766, 0121-4766)