CALCIUM CARBONATE- calcium carbonate suspension
PAI Holdings, LLC

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, in a tray of ten cups.

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

R07/20

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0766-16

Quality ®
Value

Calcium Carbonate
Oral Suspension

1250 mg/5 mL

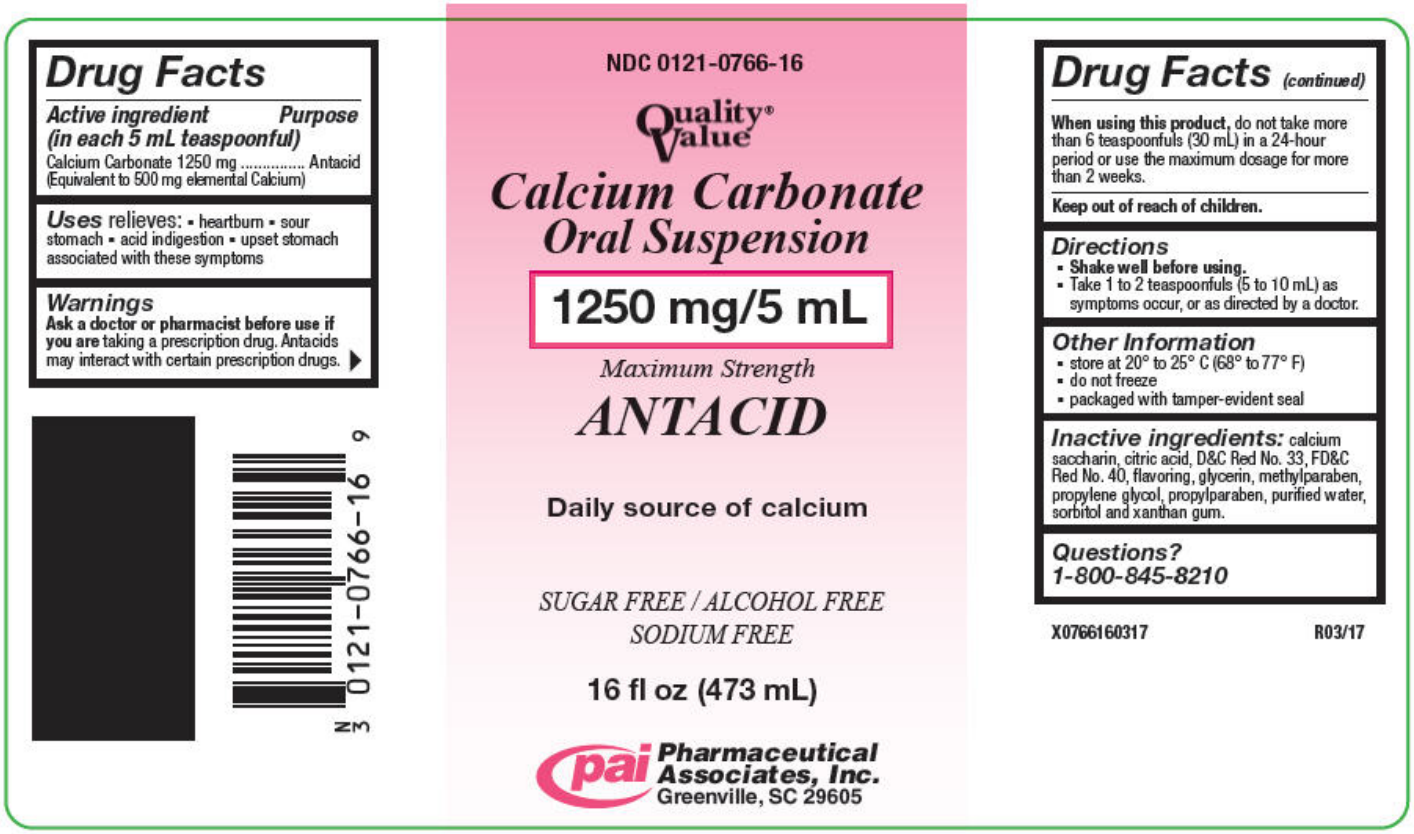
Maximum Strength
ANTACID

Daily source of calcium

SUGAR FREE / ALCOHOL FREE
SODIUM FREE

16 fl oz (473 mL)

Pharmaceutical
Associates, Inc.
Greenville, SC 29605



PRINCIPAL DISPLAY PANEL - 5 mL Cup Tray Label

Delivers **5 mL**

NDC 0121-4766-05

Calcium Carbonate Oral Suspension

1250 mg/5 mL

(equivalent to 500 mg of elemental Calcium)

ANTACID – SHAKE WELL

Package Not Child-Reistant

Pharmaceutical Associates, Inc.

Greenville, SC 29605

SEE INSERT

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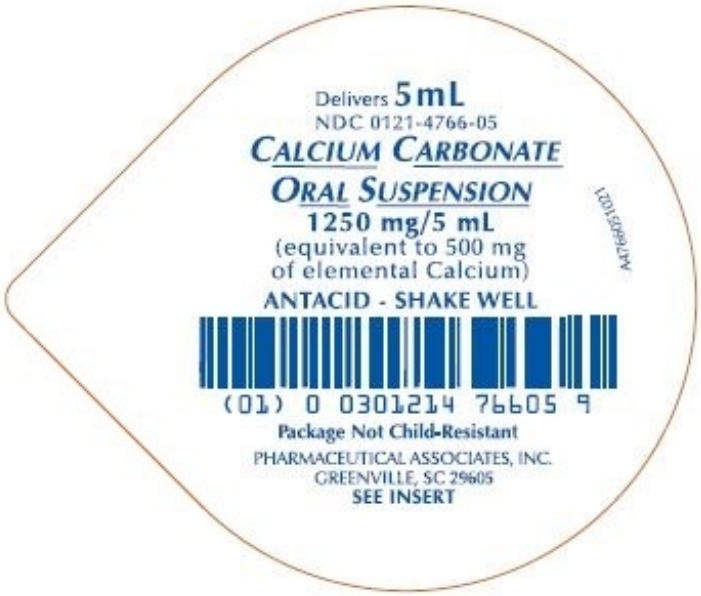

CALCIUM CARBONATE

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**
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SACCHARIN CALCIUM (UNII: 5101OP7P2I)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

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 Drug	M001	12/01/2004	

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calcium carbonate suspension

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PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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:0121-4766-05	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 Drug	M001	12/01/2004	

Labeler - PAI Holdings, LLC (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	manufacture(0121-0766, 0121-4766)

Revised: 11/2023 PAI Holdings, LLC