

**CALCIUM CARBONATE- calcium carbonate suspension**  
**PINNACLE PHARMA LLC**

*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.*

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**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:

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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.

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### **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 - 5 mL Cup Tray Label**

NDC 81646-112-05

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

Pinnacle Pharma LLC  
Charlotte, NC 28217

81646011205

**CALCIUM CARBONATE  
ORAL SUSPENSION  
1250 MG/ 5 ML**

See package insert for indications and dosage schedule

Store at controlled room temperature 20° to 25°C (68° to 77°F). Each 5 mL (one cup) contains: Calcium Carbonate 1250mg/5mL. **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**



81646-0112-05

Dosage: 5 ML

CALCIUM CARBONATE

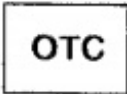
Qty: 72 CUPS



GTIN: 816460112050

Exp: MM/DD/YYYY

Lot: 123456



Distributed by: Pinnacle Pharma LLC

**Case Label**

**CALCIUM CARBONATE  
ORAL SUSPENSION  
1250 MG/ 5 ML  
ALCOHOL FREE / SUGAR FREE  
\*SHAKE WELL\* DELIVERS 5 ML**



81646011205

**DISTRIBUTED BY PINNACLE  
PHARMA**  
Exp:04/15/2021  
UDS LOT: 123456  
Mfg:PAI  
Mfg Lot: C6EA

**Cup Label**

# CALCIUM CARBONATE

calcium carbonate suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81646-112(NDC:0121-0766)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81646-112-05	05 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	12/01/2004	

## Marketing Information

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

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**Labeler** - PINNACLE PHARMA LLC (081126970)

Revised: 7/2021

PINNACLE PHARMA LLC