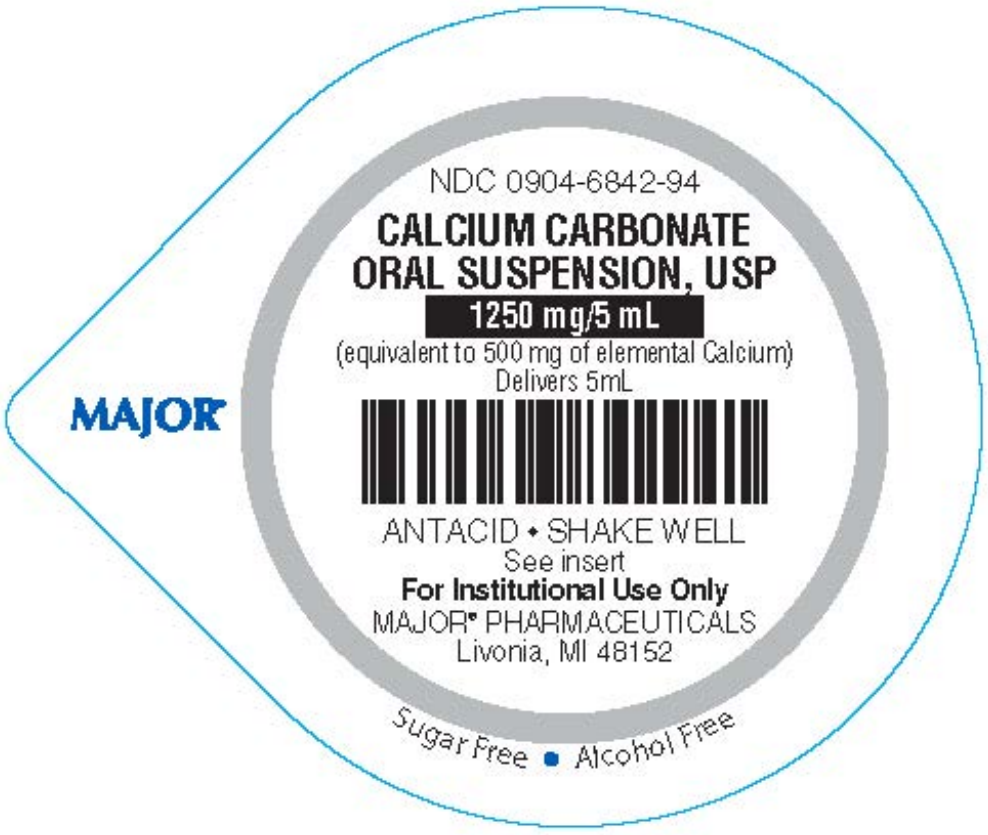
CALCIUM CARBONATE ORAL SUSPENSION- calcium carbonate suspension
Major Pharmaceuticals

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 Oral Suspension, USP 5 mL single dose cup
Major Pharmaceuticals

Major Pharmaceuticals
Calcium Carbonate Oral Suspension, USP
5 mL unit dose cup



NDC 0904-6842-94

Calcium Carbonate

Oral Suspension, USP

1250 mg/5 mL

(equivalent to 500 mg of elemental Calcium)

Delivers 5 mL

Antacid - Shake Well

See Insert

For Institutional Use Only

Major Pharmaceuticals

Livonia, MI 48152

Sugar Free - Alcohol Free

Calcium Carbonate Oral Suspension IFU 5 mL

Product Insert

Calcium Carbonate Oral Suspension, USP

NDC 0904-6842-94

10 x 5 mL Unit Dose Cups

Drug Facts

Active ingredient (in each 5 mL cup)	Purpose
Calcium Carbonate 1250 mg (Equivalent to 500 mg elemental Calcium)	Antacid

Uses ■ relieves heartburn ■ relieves acid indigestion ■ relieves sour stomach ■ relieves upset stomach associated with these symptoms

Warnings

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

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- do not exceed the maximum recommended daily dose in a 24-hour period
- do not use the maximum dosage for more than 2 weeks
- shake well before use

Dose (mL)
5-10 mL as symptoms occur Do not take more than 30 mL in 24 hours.

Other information

- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, methyl cellulose, methyl paraben, propyl paraben, purified water, sorbitol, sucralose, xanthan gum.

Questions or comments?

Call 1-800-616-2471

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MAJOR® PHARMACEUTICALS
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Rev. 12/19

Calcium Carbonate Oral Suspension

Directions

- do not exceed the maximum recommended daily dose in a 24-hour period

- do not use the maximum dosage for more than 2 weeks

- shake well before use

Dose (mL)

5-10 mL as symptoms occur

Do not take more than 30 mL in 24 hours.

Calcium Carbonate Oral Solution

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Calcium Carbonate Oral Solution

Warnings

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Calcium Carbonate Oral Solution

Inactive ingredients cherry flavor, citric acid, glycerin, methyl cellulose, methyl paraben, propyl paraben, purified water, sorbitol, sucralose, xanthan gum.

Calcium Carbonate Oral Solution

Active ingredient (in each 5 mL cup)

Calcium Carbonate 1250 mg

(Equivalent to 500 mg elemental Calcium)

Calcium Carbonate Oral Solution

Purpose

Antacid

Calcium Carbonate Oral Solution

Other information

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Calcium Carbonate Oral Suspension

Uses

relieves heartburn

relieves acid indigestion

relieves sour stomach

relieves upset stomach associated with these symptoms

CALCIUM CARBONATE ORAL SUSPENSION

calcium carbonate suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6842
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0904-6842-94	10 in 1 CASE	01/02/2020	03/02/2020
1		10 in 1 TRAY		
1		5 mL in 1 CUP; 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	01/02/2020	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Plastikon Healthcare (041717941)

Establishment

Name	Address	ID/FEI	Business Operations
Plastikon Healthcare, LLC		041717941	manufacture(0904-6842)

Revised: 2/2020 Major Pharmaceuticals