CALCIUM CARBONATE- calcium carbonate suspension
Hikma Pharmaceuticals USA 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.

Supplement Facts

CALCIUM CARBONATE Oral Suspension (not USP)

Calcium Supplement

Supplement Facts

Serving Size: 5 mL (teaspoonful)	
Amount Per Serving	**% Daily Value**
Calcium 500 mg	50 %

Active Ingredient

Each 5 mL (teaspoonful) delivers 1250 mg calcium carbonate (equivalent to 500 mg elemental calcium).

Purpose

Antacid

Keep Out of Reach of Children

Keep bottle tightly closed. **Store in a cool, dry place, out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center immediately.

Uses

Use for the prevention of calcium deficiency in adults.

Warnings

Do not use more than directed.

As with any supplement, if you are pregnant or nursing a baby, contact your healthcare professional before use.

The seal of the package bears our name, Roxane. If the seal is broken or our name does not appear, do not use.

Directions

Shake well before using. Take 5 mL (one teaspoonful) two to three times daily with meals or as directed by a physician.

Storage and Handling

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Keep from freezing.

Sodium content: 0 mg per 5 mL

Inactive Ingredients

Methylparaben, propylene glycol, propylparaben, purified water, sodium hypochlorite solution, sorbitol solution, spearmint flavor, xanthan gum.

Questions or Comments

Call 1-800-962-8364. You may also report serious side effects to this phone number.

Distr. by: **West-Ward**
Pharmaceuticals Corp.
Eatontown, NJ 07724

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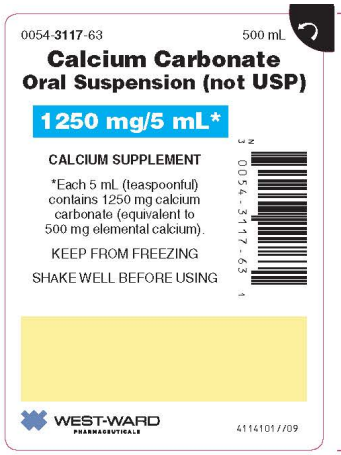
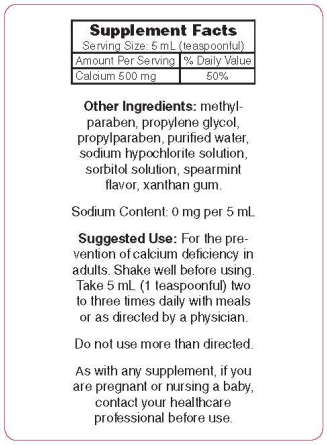
Revised November 2016

Package/Label Principal Display Panel

CALCIUM CARBONATE Oral Suspension (not USP)

0054-**3117**-63: 1250mg/5mL (provides 500mg elemental calcium per 5mL)





CALCIUM CARBONATE

calcium carbonate suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0054-3117
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
SORBITOL (UNII: 506T60A25R)	
1-PROPOXY-2-PROPANOL (UNII: 152BY1743W)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SPEARMINT (UNII: J7I2T6IV1N)	
SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0054-3117-63	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2004	05/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	11/18/2004	05/31/2024

Labeler - Hikma Pharmaceuticals USA Inc. (080189610)

Establishment

Name	Address	ID/FEI	Business Operations
West-Ward Columbus Inc.		058839929	MANUFACTURE(0054-3117)

Revised: 12/2022 Hikma Pharmaceuticals USA Inc.