CALCIUM CARBONATE ASSORTED FLAVORS- antacid tablets tablet, chewable NuCare Pharmaceuticals, 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.

Major Regular Strength Antacid 150 Chewable Tablets

Active ingredient

Calcium Carbonate USP 500mg

Purpose

Antacid

Uses

relieves:

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

Warnings

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

When using this product

- do not take more than 15 tablets in 24 hours
- If pregnant do not take more than 10 tablets in 24 hours
- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor.

Keep out of Reach of Children

Directions

- Adults and children 12 years of age and over: chew 2-4 tablets as symptoms occur, or as directed by a doctor.
- Do not take for symptoms that persist for more than 2 weeks unless advised by a doctor.

Other Information

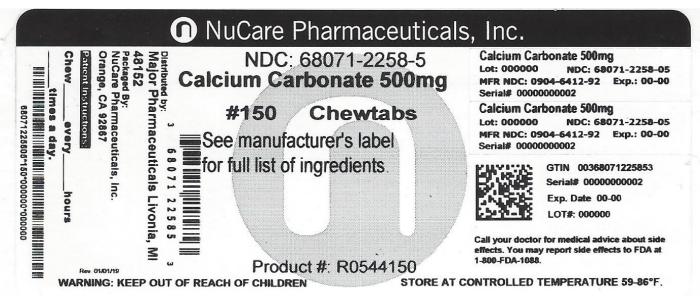
- each tablet contains: elemental calcium 200 mg
- Store at room temperature. Keep the container tightly closed

Safety sealed: Do not use if printed seal under cap is torn or missing.

Inactive ingredients

adipic acid, D&C Red No. 27 Lake, D&C Yellow No. 10 Lake, dextrose, FD&C Blue No. 1 Lake, FD&C Yellow No. 6 Lake, flavors, magnesium stearate, maltodextrin, starch, sucralose.

Package/Label Principal Display Panel



CALCIUM CARBONATE ASSORTED FLAVORS

antacid tablets tablet, chewable

_			
Drod		Intorm	STIAN
PIUU	IUCL	Inform	alivii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-2258(NDC:0904-6412)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII: 2M83C4R6ZB)	CALCIUM CARBONATE	500 mg

Inactive Ingredients

Ingredient Name	Strength
ADIPIC ACID (UNII: 76A0JE0FKJ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	16mm	
Flavor	FRUIT	Imprint Code	RP101	
Contains				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/11/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	08/12/2014	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment				
Name	Address	ID/FEI	Business Operations	
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-2258)	

Revised: 1/2022 NuCare Pharmaceuticals,Inc.