NUTRALOX- calcium carbonate tablet, chewable A-S Medication Solutions

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.

NUTRALOX

Active Ingredient (in each tablet): Calcium Carbonate 420 mg

Purpose: Antacid

Uses: Temporarily relieves

- heartburn
- sour stomach
- acid indigestion
- upset stomach

Warnings:

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

Stop use and ask a doctor if symptoms last for more than 2 weeks

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 take more than directed

Adults and children 12 years of age and over:

- thoroughly chew 2 tablets every 3 to 4 hours as symptoms occur
- do not take more than 16 tablets in 24 hours unless directed by a doctor
- do not use the maximum dose for more than 2 weeks

Children under 12 years of age: ask a doctor

Inactive Ingredients: Acacia Gum, Flavor, Magnesium Stearate, Maltodextrin, Silicon Dioxide, Starch, Sucrose

HOW SUPPLIED

Product: 50090-4612

CALCIUM CARBONATE



NUTRALOX

calcium carbonate tablet, chewable

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-4612(NDC:50332-0106)

Route of Administration ORAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
	CALCIUM CARBONATE (UNII: H0 G9 379 FGK) (CALCIUM CATION - UNII: 2M8 3C4R6 ZB)	CALCIUM CARBONATE	420 mg

Inactive Ingredients				
Ingredient Name	Strength			
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SUCRO SE (UNII: C151H8 M554)				
ACACIA (UNII: 5C5403N26O)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				

Product Characteristics					
Color	white	Score	no score		
Shape	ROUND	Size	12mm		
Flavor		Imprint Code	NLX		
Contains					

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50090-4612-0	50 in 1 BOX, UNIT-DOSE	10/15/2019		
1		2 in 1 PACKET; 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	01/20/1987		

Labeler - A-S Medication Solutions (830016429)

Establishment					
Name	Address	ID/FEI	Business Operations		
A-S Medication Solutions		830016429	RELABEL(50090-4612)		

Revised: 10/2019 A-S Medication Solutions