ROOTSALLO TOOTHPASTE- calcium carbonate, alcloxa, aminocaproic acid, dibasic calcium phosphate dihydrate gel, dentifrice rootsallo Qwell

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENTS

CALCIUM CARBONATE 10.30% ALCLOXA 0.05% Aminocaproic Acid 0.05% DIBASIC CALCIUM PHOSPHATE DIHYDRATE 0.30%

PURPOSE

Anti plaque, Anti cavities, Healthy Gums, Prevent Gingivitis and Perioodontitis, Prevent Periodontal Disease

Uses

Antiplaque, Anticavity, Healthy Gums Toothpaste

Warnings

(1) Do not swallow, gargle fully after using.

(2) If the use of this paste causes gingiva or oral cavity injury, please stop using and consult a doctor or a dentist.

(3) If childern under 6 years of age use, please apply a pea-sized amount each thime. Do not swallow. Please use under the guidance of the guardian.

(4) If children under 6 years of age accidentally ingest large amounts of the paste, please consult a doctor or a dentist immediately.

(5) Keep out of reach of children under 6 years of age.

(6) This product contains sodium benzoate, which has mild irritation to the skin, eyes and mucosa.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children under 6 years of age.

Directions

Brushing the teeth with a suitable amount

Other Information

Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light.

Questions

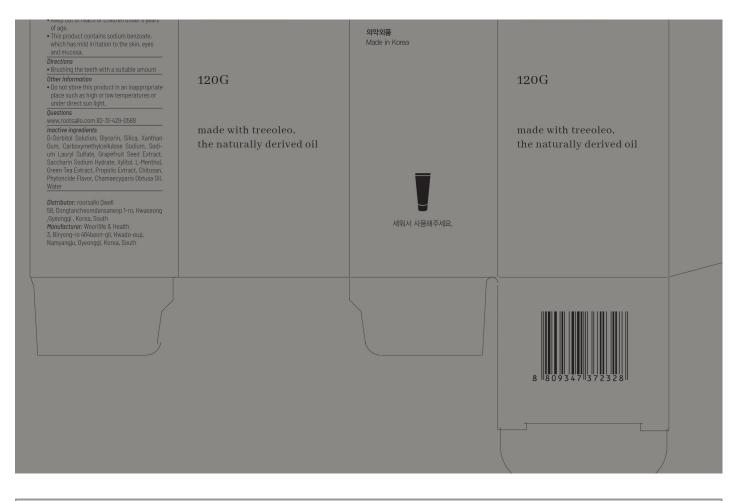
www.rootsallo.com 82-31-429-0588

Inactive ingredients

D-Sorbitol Solution, Glycerin, Silica, Xanthan Gum, Carboxymethylcellulose Sodium, Sodium Lauryl Sulfate, Grapefruit Seed Extract, Saccharin Sodium Hydrate, Xylitol, L-Menthol, Green Tea Extract, Propolis Extract, Chitosan, Phytoncide Flavor, Chamaecyparis Obtusa Oil, Water

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





ROOTSALLO TOOTHPASTE

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Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:824		50-050	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name				Basis of Strength	
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)				CALCIUM CATION	
ALCLOXA (UNII: 18B8O9DQA2) (AL	ALCLOXA		0.05 g in 100 g		
Aminocaproic Acid (UNII: U6F378 UNII:U6F3787206)	Aminocaproic Acid		0.05 g in 100 g		
			DIBASIC CALCIUM PHOSPHATE DIHYDRATE		0.30 g in 100 g
Inactive Ingredients					
Ingredient Name					gth
SORBITOL (UNII: 506T60A25R)					
Glycerin (UNII: PDC6A3C0OX)					

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

Packaging							
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:82450-050- 02	1 in 1 CARTON	12/01/2021				
1	NDC:82450-050- 01	120 g in 1 TUBE; Type 0: Not a Combination Product					
M	arketing	Information					
Μ	arketing Marketing Category	I nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			

Labeler - rootsallo Qwell (695495466)

Registrant - rootsallo Qwell (695495466)

Establishment

Name	Address	ID/FEI	Business Operations
Woorilife& Health		694860803	manufacture(82450-050)

Revised: 12/2021

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