#### 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.

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# **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

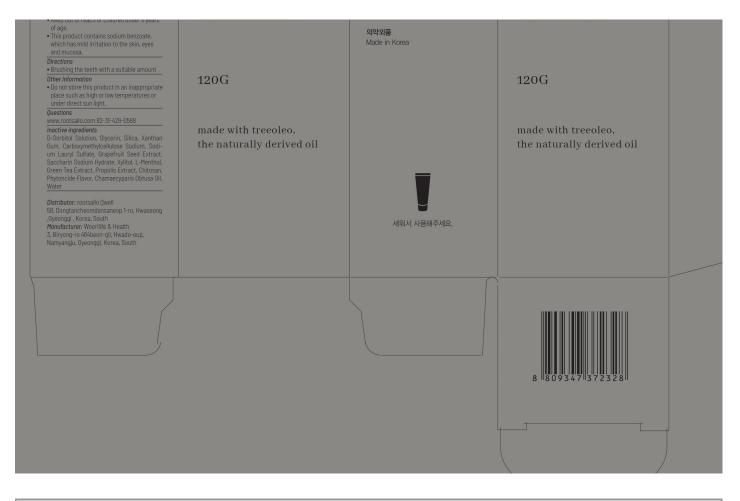
www.rootsallo.com 82-31-429-0588

#### 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**

calcium carbonate, alcloxa, aminocaproic acid, dibasic calcium phosphate dihydrate gel, dentifrice

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:824		50-050	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name				<b>Basis of Strength</b>	
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 <b>nformation</b> 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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rootsallo Qwell