

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 Periodontitis, 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 children under 6 years of age use, please apply a pea-sized amount each time. 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:82450-050
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6Z B)	CALCIUM CATION	10.30 g in 100 g
ALCLOXA (UNII: 18B809DQA2) (ALLANTOIN - UNII:344S277G0Z)	ALCLOXA	0.05 g in 100 g
Aminocaproic Acid (UNII: U6F3787206) (AMINOCAPROIC ACID - UNII:U6F3787206)	Aminocaproic Acid	0.05 g in 100 g
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) (ANHYDROUS DIBASIC CALCIUM PHOSPHATE - UNII:L11K75P92J)	DIBASIC CALCIUM PHOSPHATE DIHYDRATE	0.30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2021	

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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