

DR.EL GUM CARE TOOTH- precipitated calcium carbonate, dibasic calcium phosphate, aluminium chlorohydroxy allantoinate, aminocaproic acid paste, dentifrice
Dr. EL CO., LTD.

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.

Precipitated Calcium Carbonate
Dibasic Calcium Phosphate
Aluminium Chlorohydroxy Allantoinate
Aminocaproic Acid

For dental care

Keep out of reach of children

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician

Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years: Ask a dentist or physician

- (1) Do not swallow and rinse mouth thoroughly after use
- (2) If you experience any problems with your gums or mouth during use, discontinue use and consult your doctor.
- (3) For children under 6 years of age, use small amounts of toothpaste. And use it under the supervision of a guardian to avoid sucking or swallowing.
- (4) Consult a physician or dentist immediately if a child under 6 years old has swallowed large quantities.
- (5) Keep out of the reach of children under 6 years of age.

D-Sorbitol Solution, Aqua, Concentrated Glycerin, Sodium Cocoyl Glutamate, Xantangum, L-Menthol, Peppermint Oil, Mint Flavor, Propolis Powder, Xylitol, Green Tea Extract, Eucalyptus Extract, Chamomile Extract, Sage Extract, Aloe Extract, Taraxacum officinale Extract, Olive leaf extract, Mastic Oil

For dental use only





DR.EL GUM CARE TOOTH

precipitated calcium carbonate, dibasic calcium phosphate, aluminium chlorohydroxy allantoinate, aminocaproic acid paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72440-107
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	0.1 g in 100 g

CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	30 g in 100 g
ALCLOXA (UNII: 18B8O9DQA2) (ALCLOXA - UNII:18B8O9DQA2)	ALCLOXA	0.1 g in 100 g
AMINOCAPROIC ACID (UNII: U6F3787206) (AMINOCAPROIC ACID - UNII:U6F3787206)	AMINOCAPROIC ACID	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72440-107-01	120 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2019	

Labeler - Dr. EL CO., LTD. (694771074)

Registrant - Dr. EL CO., LTD. (694771074)

Establishment

Name	Address	ID/FEI	Business Operations
DONG IL PHARMS CO.,LTD		557810721	manufacture(72440-107)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. EL CO., LTD.		694771074	label(72440-107)

Revised: 9/2019

Dr. EL CO., LTD.