

DOLLAR SHAVE CLUB- sodium fluoride gel, dentifrice
Dollar Shave Club

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.

Dollar Shave Club

Drug Facts

Active Ingredient

Sodium fluoride 0.24%
(0.15% w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities.

Warnings

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

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Twist off cap to remove foil seal. Do not use if safety seal is missing or broken.

Directions

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice per day, or as directed by a dentist or physician.
- Do not swallow.
- Children under 6 years of age: Use a pea-sized amount and supervise until good brushing and rinsing habits are established (to minimize swallowing).
- Children under 2 years of age: Consult a dentist or a physician.

Inactive Ingredients

Sorbitol, Hydrated Silica, Glycerin, Xylitol, Purified Water, Sodium Lauryl Sulfate, Flavor, Xanthan Gum, Stevia Rebaudiana Leaf Extract, Blue 1 and Yellow 10.

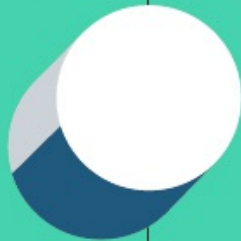
PRINCIPAL DISPLAY PANEL - 142 g Tube Label

SUPERBA

PEPPERMINT KICK

FLUORIDE GEL TOOTHPASTE

NET WT 5.0 OZ (142g)



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ORIGINAL FORMULAS. DESIGNED FOR YOU.

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MADE IN U.S.A. WITH GLOBALLY SOURCED INGREDIENTS
P09TGTU001



DOLLAR SHAVE CLUB

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69522-1112
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium fluoride (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU408O)	fluoride ion	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
Hydrated silica (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
Xylitol (UNII: VCQ006KQ1E)	
Glycerin (UNII: PDC6A3C0OX)	
Xanthan Gum (UNII: TTV12P4NEE)	
Sodium lauryl sulfate (UNII: 368GB5141J)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT (Peppermint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69522-1112-2	90 g in 1 TUBE; Type 0: Not a Combination Product	06/28/2018	
2	NDC:69522-1112-1	28 g in 1 TUBE; Type 0: Not a Combination Product	06/28/2018	
3	NDC:69522-1112-3	142 g in 1 TUBE; Type 0: Not a Combination Product	06/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/28/2018	

Labeler - Dollar Shave Club (004164494)**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	MANUFACTURE(69522-1112)