

CVS PHARMACY PRO DEFENSE- fluoride paste, dentifrice

CVS Pharmacy

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.

5820278 CVS Pro Defense Whitening

Active ingredient

Stannous Fluoride (0.454% w/w)

Purpose

Anticavity/Antigingivitis

Uses

- aids in the prevention of dental cavities
- helps control bleeding gums
- helps interfere with harmful effects of plaque associated with gingivitis

Warnings

When using this product, discontinue use if irritation occurs.

Stop use and ask a dentist if

- gingivitis, bleeding or redness persists for more than 2 weeks
- if you have painful or swollen gums, pus from the gum line, loose teeth or increasing space between teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

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.

Directions

Adults and children 2 years of age and older:

- Brush teeth thoroughly preferably after each meal or at least twice a day and not more than 3 times a day or as directed by a dentist or doctor. Minimize swallowing. Spit out after brushing.
- To minimize swallowing for children under 6 years of age, use a pea-sized amount and supervise brushing until good habits are established.

Children under 2 years of age: consult a dentist or doctor

Other information

- products containing Stannous Fluoride may cause surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent, and may be removed by your dentist.
- This product is specially formulated to help prevent staining.
- Store below 77F (25C)

- Keep tube capped when not in use.

Inactive ingredients glycerin, water, hydrated silica, pentasodium triphosphate, cellulose gum, cocamidopropyl betaine, titanium dioxide, sodium lauryl sulfate, flavor, sodium saccharin

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-872
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION -		FLUORIDE ION	0.454 g

UNII:Q80VPU408O)		FLUORIDE ION	in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
WATER (UNII: 059QF0KO0R)				
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-872-19	1 in 1 CARTON	06/01/2017	08/31/2024
1		96.4 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	
OTC monograph final	part355	06/01/2017		

Labeler - CVS Pharmacy (062312574)

Registrant - Lornamead Inc. (078584069)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(69842-872)