

RITE AID PRO DEFENSE WHITENING- stannous fluoride paste, dentifrice **Rite Aid**

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.

Rite Aid Pro Defense Whitening Toothpaste

Drug Facts

Active ingredient

Stannous fluoride 0.454% (w/w)

Purpose

Anticavity / Anti-gingivitis

Uses

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

Warnings

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 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 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 your dentist.
- This product is specifically formulated to help prevent staining
- store below 77°F (25°C)
- 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:

RITE AID

30 HUNTER LANE

CAMP HILL, PA 17011

RITE AID® PHARMACY

oral care

pro defense

daily fluoride anticavity & anti-gingivitis toothpaste

whitening

NET WT 3.4 OZ (96.4 g)

<p>Rite Aid Pro Defense Toothpaste is specially formulated with stannous fluoride to lessen bleeding gums and fight gingivitis by removing plaque and keeping the seal between your teeth and gum line tight. Use Rite Aid Pro Defense Toothpaste everyday to help prevent cavities, fresher breath and whiten teeth.</p>	<p>DISTRIBUTED BY: RITE AID 30 HUNTER LANE CAMP HILL, PA 17011</p>	<p>SATISFACTION RITE AID GUARANTEE IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.</p>	#368775									
	<p>Contains stannous fluoride, clinically proven to help control bleeding gums.</p>											
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<p><small>*This product is not manufactured or distributed by GSK, owners of the registered trademark parodontax™.</small></p>												

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stannous fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6034
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.454 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	

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:11822-6034-9	1 in 1 CARTON	03/03/2019	
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 not final	part356	03/03/2019	

Labeler - Rite Aid (014578892)

Registrant - Lornamead Inc. (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(11822-6034)

Revised: 1/2023

Rite Aid