SMILE ACTIVE PRO TARTAR CONTROL FLUORIDE- sodium fluoride paste Guthy-Renker LLC

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.

Smile Active Pro Tartar Control Fluoride Toothpaste

Drug Facts

Active ingredient

Sodium Fluoride 0.248% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

• Helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age. If more than for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age or older, brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
- To minimize swallowing, use a pea-sized amount for children under 6.
- Supervise children's brushing until good habits are established.
- Children under 2 years of age, ask a dentist or physician.

Other information

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

Inactive ingredients

Sorbitol, Hydrated Silica, Water, Glycerin, Xylitol, Pentasodium Triphosphate, Cocamidopropyl Betaine, Titanium Dioxide, Flavor, Xanthan Gum, Sodium Methyl Cocoyl Taurate, Sucralose, Glycine, Sodium Ascorbyl Phosphate, Sodium Hyaluronate, Hydrolyzed Hyaluronic Acid.

Questions or comments?

888-575-5700 www.smileactives.com

Distributed by: Oral Care Products, LLC El Segundo, CA 90245

PRINCIPAL DISPLAY PANEL - 170 g Tube Label

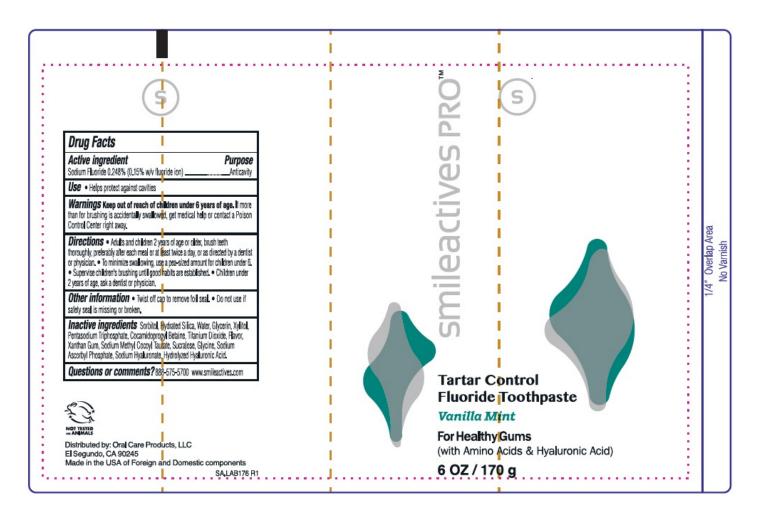
smileactives PRO™

Tartar Control Fluoride Toothpaste

Vanilla Mint

For Healthy Gums (with Amino Acids & Hyaluronic Acid)

6 OZ / 170 g



SMILE ACTIVE PRO TARTAR CONTROL FLUORIDE

sodium fluoride paste

Product Infor	mation					
Product Type		HUMAN OTC DRUG Item Code		ode (Source)	(Source) NDC:70605-039	
Route of Admini	stration	DENTAL				
Active Ingredi	ent/Active	Moiety				
Ingredient Name				Basis of Strength		Strength
Sodium Fluoride (JNII: 8ZYQ1474	4W7) (Fluoride Ion - UNII:	Q80VPU4080	D) Sodium Fluoride	9	1.5 mg in 1 g
Inactive Ingre	dients					
Ingredient Name						Strength
Sorbitol (UNII: 506T60A25R)						
Hydrated Silica (U		9)				
Nater (UNII: 059QF						
Glycerin (UNII: PDC	6A3C0OX)					
Kylitol (UNII: VCQ00	6KQ1E)					
Sodium Tripolyph	osphate Anhy	drous (UNII: 9SW4PFD2F	Z)			
Cocamidopropyl B	etaine (UNII: 5	50CF3011KX)				
Fitanium Dioxide	UNII: 15FIX9V2	P)				
Sucralose (UNII: 96	K6UQ3ZD4)					
Sodium Methyl Co	coyl Taurate	(UNII: JVL98CG53G)				
Kanthan Gum (UNI	: TTV12P4NEE)					
Sodium Ascorbyl F	hosphate (UN	III: 836SJG51DR)				
Glycine (UNII: TE76	60XO1C)					
Hyaluronate Sodiu	um (UNII: YSE9I	PPT4TH)				
Packaging						
# Item Code	Pae	kage Description		Marketing Start Date	Marl	ceting End Date
NDC:70605-039- 22	57 g in 1 TUBE Product	E; Type 0: Not a Combina	ation 04	4/01/2023		
NDC:70605-039-	170 g in 1 TUE Product	BE; Type 0: Not a Combin	nation 04	4/01/2023		
96						
96						
96	nformat	ion				
Marketing Marketing Category		ion tion Number or Mon Citation	ograph	Marketing Start Date	Mai	rketing End Date

Labeler - Guthy-Renker LLC (948861877)