PARODONTAX- stannous fluoride paste GlaxoSmithKline Consumer Healthcare Holdings (US) 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.

Drug Facts

Active ingredient

Stannous fluoride 0.454 % (0.15 % w/v fluoride ion)

Purposes

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,

if irritation occurs discontinue use.

Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks.
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the 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:
- apply toothpaste onto a toothbrush.
- brush teeth thoroughly, preferably after each meal 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 and rinsing until good habits are established.
- **children under 2 years of age:** Consult a dentist or doctor.

Other information

- products containing stannous fluoride may produce surface staining of the teeth. Adequate toothbrushing 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 25°C (77°F)

Inactive ingredients

glycerin, PEG-8, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, polyacrylic acid, cocamidopropyl betaine, sodium saccharin

Questions or comments?

Call toll-free **1-855-328-5202**

Principal Display Panel

NDC 0135-0598-01

parodontax™

CLEAN MINT

DAILY FLUORIDE ANTICAVITY AND ANTIGINGIVITIS TOOTHPASTE

New

CLINICALLY PROVEN \cdot HEALTHY GUMS AND STRONG TEETH

Helps prevent bleeding gums

NET WT

3.4 OZ (96.4 g)

parodontax[™] toothpaste – clinically proven to help control bleeding gums

Why spitting blood needs to be treated.

Healthy gums are fundamental for strong teeth, and healthy gums don't bleed. If your gums bleed when brushing or flossing, this can be a sign of gum disease. Gingivitis is an early sign of gum disease and is caused by plaque build up around the gum line. If left untreated, this may lead to red and swollen gums.

parodontaxTM is a daily toothpaste that is clinically proven to help control bleeding gums.

parodontx[™] helps fight the cause of bleeding gums by removing significantly more plaque than a sodium monofluorophosphate toothpaste. With daily use it strengthen teeth and helps keep the seal between gums and teeth tight. Use it every day with confidence since it also **prevents cavities**, **freshens breath and helps whiten. Helps prevent bleeding gums – for healthier gums and stronger teeth**.

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GSK Consumer Healthcare



Principal Display Panel

NDC 0135-0599-02

parodontax™

EXTRA FRESH

DAILY FLUORIDE ANTICAVITY AND ANTIGINGIVITIS TOOTHPASTE

New

CLINICALLY PROVEN \cdot HEALTHY GUMS AND STRONG TEETH

Helps prevent bleeding gums

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GSK Consumer Healthcare

Warren, NJ 07059

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Principal Display Panel NDC 0135-0601-01 parodontax[™] WHITENING DAILY FLUORIDE ANTICAVITY AND ANTIGINGIVITIS TOOTHPASTE New

CLINICALLY PROVEN · HEALTHY GUMS AND STRONG TEETH

Helps prevent bleeding gums

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GSK Consumer Healthcare

Warren, NJ 07059

105407XA



stannous fluoride paste					
initia do Intorne puble					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC	C:0 135-0 59	8
Route of Administration	DENTAL				
Active Ingredient/Active Mo	iety				
Ir	ıgredient Name		Basis of Stren	igth St	rength
STANNOUS FLUORIDE (UNII: 3FTR4	4B32Q) (FLUORIDE ION - U	NII:Q80VPU408O)	FLUORIDE ION	1.5 1	ng in 1 g
Inactive Ingredients					
0	Ingredient Na	ıme		5	Strengt
GLYCERIN (UNII: PDC6A3C0OX)	0				0
POLYETHYLENE GLYCOL 400 (UN	II: B697894SGQ)				
HYDRATED SILICA (UNII: Y6O7T4G8	P9)				
SO DIUM TRIPO LYPHO SPHATE ANI	HYDROUS (UNII: 9SW4PFD)	2FZ)			
SODIUM LAURYL SULFATE (UNII: 3	68GB5141J)				
TITANIUM DIO XIDE (UNII: 15FIX9V2	JP)				
CARBOMER HOMOPOLYMER TYP	E B (ALLYL PENTAERYTH	IRITOL CROSSLINKED) (UNII: HHT01ZNK31	1)	
COCAMIDOPROPYL BETAINE (UNI	: 50CF3011KX)				
SACCHARIN SODIUM (UNII: SB8ZUX	(40 TY)				
Product Characteristics					
	WHITE	6			
Color		Score			
Shape		Size			
Flavor	MINT	Imprint Code			
Contains					
- 1 .					
Packaging # Item Code	Package Description		Start Date Ma	-	

 $12/19/20\,16$

1 NDC:0135-0598-01 1 in 1 CARTON

1 96.4	4 g in 1 TUB	E; Type 0: Not a Combination Pr	oduct				
Marketing Inform	nation						
Marketing Category		on Number or Monograph (Citation	Marketing	Start Date	Marketi	ng End Date
OTC monograph not final	part356	U .		12/19/2016			5
PARODONTAX							
stannous fluoride paste							
Product Information	l						
Product Type		HUMAN OTC DRUG	Ite m Co	de (Source))	NDC:0135-	0599
Route of Administration		DENTAL					
Active Ingredient/Ac	tive Moie	ety					
	Ing	gredient Name			Basis of S	trength	Strength
STANNOUS FLUORIDE (U	JNII: 3FTR44	B32Q) (FLUORIDE ION - UNII:Q	80 VPU40	80)	FLUORIDE IO	ON	1.5 mg in 1 g
Inactive Ingredients							
		Ingredient Name					Strength
GLYCERIN (UNII: PDC6A3C0OX)							
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)							
HYDRATED SILICA (UNII: Y6O7T4G8P9)							
SODIUM TRIPOL YPHO SPHATE ANHYDROUS (UNII: 9 SW4PFD2FZ)							
SODIUM LAURYL SULFATE (UNII: 368GB5141J)							
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)							
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31) COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)							
	SACCHARIN SO DIUM (UNII: SB8ZUX40 TY)						
	n. 50620A						

Product Characteristics					
Color	WHITE	Score			
Shape		Size			
Flavor		Imprint Code			
Contains					
Contains					

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0599-01	1 in 1 CARTON	12/19/2016	
1		23 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0599-02	1 in 1 CARTON	12/19/2016	
2		96.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information							
		tion Number or Monogra	nh Citati	on Markating	Ctart Data	Markat	ng End Data
Marketing Catego OTC monograph not fin		tion Number or Monograph Citation Marketin 12/19/2016			ng Start Date Marketing En		ing End Date
OTC monograph not m	lai partoso			12/13/2010			
PARODONTA	X						
stannous fluoride pa							
ourino do maorido pa							
Product Informa	tion						
Product Type		HUMAN OTC DRUG	Itor	n Code (Source	•	NDC ·0 135	-0601
	•		Iter	li Code (Source	e) NDC:0135-0601		-0001
Route of Administra	tion	DENTAL					
A other the second							
Active Ingredien		0			D : (0		
		igredient Name			Basis of S	•	Strength
STANNOUS FLUORII	JE (UNII: 3FTR4	4B32Q) (FLUORIDE ION - U	INII:Q80VI	204080)	FLUORIDE I	ON	1.5 mg in 1 g
Inactive Ingredie	nts						
macuve ingreute	1105	Ingredient Na	mo				Strength
GLYCERIN (UNII: PDC	6A3C0OX)	Ingreutent ing	inc				Strength
POLYETHYLENE GL		II: B697894SGO)					
HYDRATED SILICA (U							
		HYDROUS (UNII: 9SW4PFD	2FZ)				
SODIUM LAURYL SU	LFATE (UNII: 3	68GB5141J)					
TITANIUM DIO XIDE (UNII: 15FIX9V2.	JP)					
		E B (ALLYL PENTAERYTH	IRITOL C	ROSSLINKED) (UNII: HHT01Z	NK31)	
CO CAMIDO PRO PYL							
SACCHARIN SODIUM	UNII: SB8ZUX	(40 TY)					
Product Characte	victics						
Color	risucs	WHITE	Score				
Shape			Size				
Flavor							
Contains							
Contains							
Packaging							
# Item Code		Package Description		Marketing	Start Date	Marketi	ng End Date
	1 in 1 CARTON	U		12/19/2016			
1	96.4 g in 1 TUE	IBE; 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	12/19/2016				

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 10/2016

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC