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 25ºC (77ºF)

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 · 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.

parodontax™ 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**.

Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

105131XA

Principal Display Panel

NDC 0135-0599-02

parodontax™

EXTRA FRESH

DAILY FLUORIDE ANTICAVITY AND ANTIGINGIVITIS TOOTHPASTE

New

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Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

105133XA

Principal Display Panel

NDC 0135-0601-01

parodontax™

WHITENING

DAILY FLUORIDE ANTICAVITY AND ANTIGINGIVITIS TOOTHPASTE

New

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Helps prevent bleeding gums

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GSK Consumer Healthcare

Warren, NJ 07059

105407XA

PARODONTAX

stannous fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0598
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

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:0135-0598-01	1 in 1 CARTON	12/19/2016	

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	12/19/2016	

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stannous fluoride paste

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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

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OTC monograph not final	part356	12/19/2016	

PARODONTAX

stannous fluoride paste

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

Revised: 10/2016 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC