# CREST PRO-HEALTH- stannous fluoride paste, dentifrice The Procter & Gamble Manufacturing Company

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.

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Crest® Pro-Health™ Clean Mint

## **Drug Facts**

Active ingredient
Stannous fluoride 0.454%
(0.14% w/v fluoride ion)

## **Purposes**

Anticavity, antigingivitis, antisensitivity toothpaste

### Uses

- aids in the prevention of cavities
- helps prevent gingivitis
- helps interfere with the harmful effects of plaque associated with gingivitis
- helps control plaque bacteria that contribute to the development of gingivitis
- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact

## Warnings

When using this product do not use for sensitivity longer than four weeks unless recommended by a dentist.

Stop use and ask a dentist if the sensitivity problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care.

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or

contact a Poison Control Center right away.

## **Directions**

- adults and children 12 yrs. & older: apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist. Make sure to brush all sensitive areas of the teeth.
- do not swallow
- children under 12 yrs.: ask a dentist

## 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 Crest is specially formulated to help prevent staining
- see your dentist regularly

## **Inactive ingredients**

water, sorbitol, hydrated silica, sodium lauryl sulfate, carrageenan, sodium gluconate, flavor, xanthan gum, zinc citrate, stannous chloride, sodium hydroxide, sodium saccharin, sucralose, titanium dioxide, blue 1

## Questions?

1-800-594-4158 DISTR. BY PROCTER & GAMBLE, CINCINNATI, OH 45202 SMOOTH FORMULA

Crest® PRO-HEALTH™

FLUORIDE TOOTHPASTE FOR ANTICAVITY, ANTIGINGIVITIS AND SENSITIVE TEETH

**CLEAN MINT** 

 $CAVITIES \mid GINGIVITIS \mid SENSITIVITY \mid PLAQUE\ TARTAR \mid WHITENING \mid FRESHENS\ BREATH$ 

NET WT 4.6 OZ (130g)



## **CREST PRO-HEALTH**

stannous fluoride paste, dentifrice

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37000-888

Route of Administration DENTAL

## **Active Ingredient/Active Moiety**

Ingredient Name
Basis of Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80 VPU408O)
FLUORIDE ION
1.4 mg in 1 g

## Inactive Ingredients

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CARRAGEENAN (UNII: 5C69 YCD2YJ)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ZINC CITRATE (UNII: K72BDEX9B)	

SORBITOL (UNII: 506T60A25R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	blue	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:37000-888-04	1 in 1 CARTON	12/19/2016		
1		130 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:37000-888-06	1 in 1 CARTON	12/19/2016		
2		178 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:37000-888-03	1 in 1 CARTON	12/19/2016		
3		93 g in 1 TUBE; Type 0: Not a Combination Product			
4	NDC:37000-888-09	2 in 1 CELLO PACK	12/19/2016		
4		1 in 1 CARTON			
4		130 g in 1 TUBE; Type 0: Not a Combination Product			
5	NDC:37000-888-01	1 in 1 CARTON	12/19/2016		
5		24 g in 1 TUBE; Type 0: Not a Combination Product			
6	NDC:37000-888-12	3 in 1 CELLO PACK	12/19/2016		
6		1 in 1 CARTON			
6		130 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	12/19/2016	

## **Labeler** - The Procter & Gamble Manufacturing Company (004238200)

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