

**HEB EXTRA WHITENING- fluoride paste, dentifrice**  
**HEB**

*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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**Drug Facts**

**Active ingredient**

Stannous fluoride 0.454% (0.16% w/v fluoride ion).....Anticavity, Antisensitivity

**Uses**

- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact
- aids in the prevention of dental cavities

**When using this product** do not use longer than 4 weeks unless recommended by a dentist or physician. **Stop use and ask a dentist if** the sensitivity problem 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**

Brush teeth thoroughly for at least one 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

Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. **Children under 12 years of age:** ask a dentist.

**Other Information**

*Store in a cool dry place. Keep tube capped when not in use.*

**Inactive ingredients**

water, hydrated silica, glycerin, propylene glycol, PEG-6, sodium tripolyphosphate, zinc lactate, trisodium phosphate, monosodium phosphate, flavor, sodium lauryl sulfate, sodium gluconate, carrageenan, sodium saccharin, polyethylene, xanthan

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<b>Drug Facts</b>		<b>Drug Facts</b> (continued)	<b>Drug Facts</b> (continued)
<b>Active ingredient</b> Stannous fluoride 0.454% (0.16% w/v Fluoride ion)	<b>Purpose</b> Anticavity, Antisensitivity	<ul style="list-style-type: none"> <li>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.</li> </ul>	<b>Other information</b> <ul style="list-style-type: none"> <li>Products containing stannous fluoride may produce surface staining of the teeth</li> <li>Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist</li> <li>See your dentist regularly</li> </ul>
<b>Uses</b> <ul style="list-style-type: none"> <li>aids in the prevention of dental cavities</li> <li>builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact</li> </ul>		<b>Directions</b> <ul style="list-style-type: none"> <li>Adults and children 12 years of age and older: apply at least a 1-inch strip of the product onto a soft bristled toothbrush. Brush teeth thoroughly for at least one minute, twice a day (morning and evening) or as recommended by a dentist. Make sure to brush all sensitive areas of the teeth.</li> <li>Do not swallow</li> <li>Children under 12 years of age: ask a dentist</li> </ul>	<b>Inactive ingredients</b> water, hydrated silica, glycerin, propylene glycol, PEG-6, sodium tripolyphosphate, zinc lactate, trisodium phosphate, monosodium phosphate, flavor, sodium lauryl sulfate, sodium gluconate, carrageenan, sodium saccharin, polyethylene, xanthan gum, titanium dioxide, mica, blue 1
<b>Warnings</b> <ul style="list-style-type: none"> <li>When using this product do not use for sensitivity longer than four weeks unless recommended by a dentist.</li> <li>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.</li> </ul>		<b>Store in a cool, dry place. Keep tube capped when not in use.</b> <b>Questions or Comments? CALL 1-877-777-2743</b>	

HE-B Same Active Ingredient as Crest® Pro-Health\* Fresh Mint

# HEALTH-PROTECTION

Stannous Fluoride Toothpaste

EXTRA WHITENING

For Sensitive Teeth • Whitens Teeth • Freshens Breath  
Fights Cavities, Plaque & Tartar

NET WT. 6 OZ (170g)

HE-B Same Active Ingredient as Crest® Pro-Health\* Fresh Mint

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H-E-B Health-Protection toothpaste delivers comprehensive protection for your teeth against sensitivity and all these other areas that dentists check the most:

- Fights Cavities
- Fights Plaque
- Fights Tartar
- Whitens Teeth
- Freshens Breath

**GUARANTEE**  
We believe the high quality of this H-E-B product makes it an outstanding value. We hope you'll agree. If not, we'll cheerfully refund your money. Thanks for shopping with us.

MADE WITH PRIDE AND CARE FOR H-E-B,  
SAN ANTONIO, TX 78204  
MADE IN USA

\* This product is not manufactured or distributed by Procter & Gamble, distributor of Crest® Pro-Health

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**EXTRA WHITENING**

For Sensitive Teeth • Whitens Teeth • Freshens Breath  
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NET WT. 6 OZ (170g)

**Drug Facts**

**Active ingredient**  
Stannous Fluoride 0.454%  
(0.16% w/v Fluoride Ion)

**Purpose**  
Anticavity,  
Antisensitivity

**Uses** • aids in the prevention of dental cavities  
• helps increasing protection against painful sensitivity  
of teeth due 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 doctor** 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 years of age and older: apply at  
least a 1-inch strip of the product onto a soft bristled  
toothbrush. Brush teeth thoroughly for at least one  
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 years of age: ask a dentist

**Other information**

• Products containing stannous fluoride may produce  
surface staining of the teeth  
• Adequate tooth brushing may prevent these stains  
which are not harmful or permanent and may be  
removed by your dentist  
• See your dentist regularly

**Store in a cool, dry place.  
Keep tube capped when not in use.**

**Questions or Comments?**  
CALL 1-877-777-2743

**MADE WITH PRIDE AND CARE FOR H-E-B,  
SAN ANTONIO, TX 78244 / MADE IN USA**



**GUARANTEE**  
We believe the high quality of this  
H-E-B product makes it an outstanding  
value. We hope you'll agree. If not,  
we'll cheerfully refund your money.  
Thanks for shopping with us.

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Procter & Gamble, distributor of CREST® Pro-Health

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## HEB EXTRA WHITENING

fluoride paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-171
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.4540 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ZINC LACTATE (UNII: 2GXR25858Y)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)
SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J)
SODIUM GLUCONATE (UNII: R6Q3791S76)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
XANTHAN GUM (UNII: TTV12P4NEE)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM PHOSPHATE (UNII: SE337SVY37)
CHONDRUS CRISPUS (UNII: OQS23HUA1X)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-171-19	1 in 1 CARTON		
1	NDC:37808-171-12	170 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/01/2012	

**Labeler** - HEB (007924756)

**Registrant** - Lornamead (126440440)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(37808-171) , pack(37808-171)