

## **H E B RESTORE AND DEFEND- fluoride paste, dentifrice**

### **HEB**

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**5820230, 5820273 HEB Sensitive Restore and Defend**

#### ***Drug Facts***

##### ***Active ingredients***

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

##### ***Purpose***

Anticavity/Antihypersensitivity

##### ***Uses***

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

##### ***Warnings***

**When using this product,** if irritation occurs discontinue use.

##### **Stop use and ask a dentist if:**

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- pain/sensitivity still persists after 4 weeks of use

**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 bristle toothbrush.

- Brush teeth thoroughly for at least one minute, preferably after each meal or at least twice a day (morning and evening) or as directed by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
- Do not swallow.
- **Children under 12 years of age:** consult a dentist or doctor.

***Inactive ingredients*** glycerin, water, hydrated silica, pentasodium triphosphate, flavor, cocamidopropyl betaine, sodium lauryl sulfate, titanium dioxide, cellulose gum, sodium saccharin

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

MADE WITH PRIDE AND CARE FOR H-E-B®

SAN ANTONIO, TX 78204

***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.

- this product is specifically formulated to help prevent staining.

COMPARE TO SENSODYNE® REPAIR & PROTECT EXTRA FRESH\*

EXTRA FRESH MINT



FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH & CAVITY PROTECTION

NET WT. 3.4 OZ (96.4 g)



EVERYDAY PROTECTION FOR SENSITIVE TEETH

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REMOVES STAINS FOR WHITER TEETH



CONTAINS FLUORIDE FOR CAVITY PROTECTION



FRESHENS BREATH



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





16728-2409

**Drug Facts**

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**Drug Facts (continued)**

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**Questions or comments?** 1-877-777-2743

\*THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY HALEON US HOLDINGS LLC, OWNER OF THE REGISTERED TRADEMARK SENSODYNE®.

# H E B RESTORE AND DEFEND

fluoride paste, dentifrice

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-230
Route of Administration	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.15 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SODIUM TRIPOLYPHOSPHATE ANHYDROUS</b> (UNII: 9SW4PFD2FZ)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-230-09	1 in 1 CARTON	07/01/2014	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:37808-230-92	2 in 1 CARTON	02/21/2019	
2		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 Drug	M021	07/01/2014	

**Labeler** - HEB (007924756)

**Registrant** - Lornamead Products (119559733)

## Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(37808-230)

