# HEB EXTRA WHITENING- sodium fluoride and potassium nitrate 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 ingredients / Purpose**

Potassium nitrate 5%......Antihypersensitivity Sodium fluoride 0.24% (0.15% w/v fluoride ion).....Anticavity

#### 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. **See your dentist if** the problem worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

**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, preferably after each meal or at least twice a day (morning and evening) or as recommended by a dentist or physican. Make sure to brush all sensitive areas of the teeth.

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

#### Other Information

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

## **Inactive ingredients**

cocamidopropyl betaine, flavor, glycerin, hydrated silica, PEG-8, sodium hydroxide, sodium methyl cocoyl taurate, sodium saccharin, sodium tripolyphosphate, sorbitol, titanium dioxide, water, xanthan gum

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## Drug Facts

## Active ingredients Purpose

Potassium nitrate 5% .... Antihypersensitivity Sodium fluoride 0.24%..... (0.15% w/v fluoride inn)

**Uses** • builds increasing protection against painful sensitivity of the teeth • aids in the prevention of dental cavities

**Warnings** 

It pain/sansitivity still persists after 4 weeks of use, please visit your dentist. • Stop use and ask a dentist if the problem worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. • 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 recommended 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.

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

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

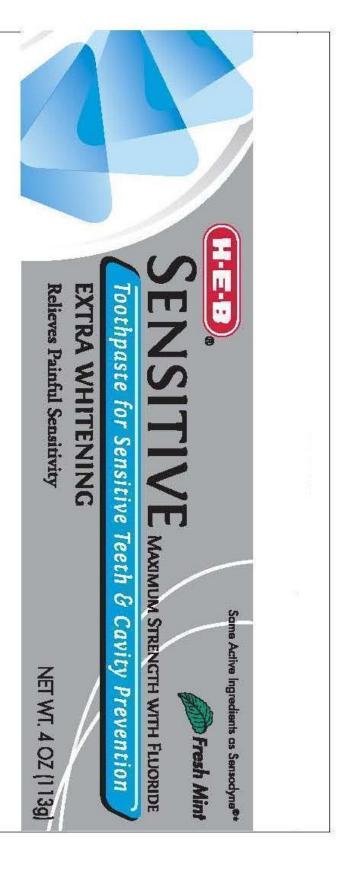
made with prede and care for H-E-B, SAN ANTONIO, TX 78204 MADE IN USA

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.

"This product is not manufactured or distributed by GaouSmithKline, owners of the trademark Sensodyne®

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fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:37808-961
Route of Administration	DENTAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	SODIUM FLUORIDE	0.24 g in 100 g
POTASSIUM NITRATE (NITRATE ION)	POTASSIUM NITRATE	5.0 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER		
SACCHARIN SO DIUM		
SODIUM TRIPOLYPHOSPHATE		
POLYETHYLENE GLYCOL 400		
SORBITOL		
TITANIUM DIO XIDE		
SO DIUM HYDRO XIDE		
GLYCERIN		
XANTHAN GUM		
HYDRATED SILICA		
CO CAMIDO PRO PYL BETAINE		
SODIUM METHYL COCOYL TAURATE		

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

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-961-19	1 in 1 CARTON		
1	NDC:37808-961-12	113 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	0 1/20/20 11	

## **Labeler** - HEB (007924756)

## Registrant - Lornamead (126440440)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(37808-961), pack(37808-961)

Revised: 11/2012 HEB