# HYVEE MAXIMUM STRENGTH- fluoride paste, dentifrice HyVee Inc

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.

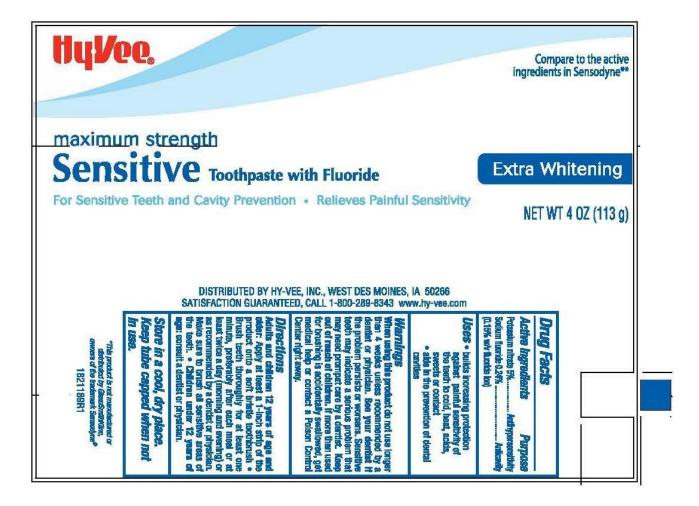
#### Inactive ingredients

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

mm1.jpg



mm2.jpg



### HYVEE MAXIMUM STRENGTH

fluoride paste, dentifrice **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:42507-189 **Route of Administration** DENTAL **Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) SODIUM FLUORIDE 0.24 g in 100 g POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII: T93E9Y2844) NITRATE ION 5.0 g in 100 g **Inactive Ingredients Ingredient** Name Strength WATER (UNII: 059QF0KO0R) SACCHARIN SODIUM (UNII: SB8ZUX40TY)

SODI	UM TRIPOLYPHOSP	HATE (UNII: 5HK03SA80J)								
POLY	ETHYLENE GLYCO	L 400 (UNII: B697894SGQ)								
SORE	BITOL (UNII: 506T60	A25R)								
TITA	NIUM DIO XIDE (UNII:	15FIX9V2JP)								
SODIUM HYDROXIDE (UNII: 55X04QC32I)										
GLYCERIN (UNII: PDC6A3C0OX)										
XANTHAN GUM (UNII: TTV12P4NEE)										
HYDF	ATED SILICA (UNII: )	Y6O7T4G8P9)								
COC	AMIDOPROPYL BET	AINE (UNII: 50CF3011KX)								
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)										
Proc	luct Characterist	ics								
Color			Score	Score						
Shape			Size							
Flavor		MINT (mint)	Imprin	nprint Code						
Conta	ains									
Pacl	aging									
#	Item Code	Package Description	Marketing	g Start Date	Ma	rketing End Dat	e			
1 ND	C:42507-189-99	1 in 1 CARTON								
1 ND	C:42507-189-92	113 g in 1 TUBE								
Mai	rketing Inforn	nation								
	rketing Category		pplication Number or Monograph Citation		Marketing Start Date		Date			
		part356		0 1/20 /20 11		Marketing End	Jaie			
OTC 1				01/20/2011						

## Labeler - HyVee Inc (006925671)

## Registrant - Lornamead (126440440)

Establishment								
Name	Address	ID/FEI	Business Operations					
Lornamead		126440440	manufacture(42507-189) , pack(42507-189)					

Revised: 11/2012

HyVee Inc