

## **HYVEE BRILLIANT WHITE- sodium 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**

Sodium fluoride 0.243% .....Anticavity

#### **Uses**

- aids in the prevention of dental cavities

Children under 2 years of age, consult a dentist or doctor

**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 2 years of age and older:** brush teeth thoroughly preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to avoid swallowing). Supervise children as necessary until capable of using without supervision.

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**

water, sorbitol, hydrated silica, disodium pyrophosphate, sodium lauryl sulfate, flavor, cellulose gum, xanthan gum, carbomer, sodium saccharin, sodium hydroxide, mica, titanium dioxide, blue 1 lake, polyethylene

mm1.jpg

<b>Drug Facts</b>		<b>Drug Facts</b> (continued)	
<b>Active ingredient</b> Sodium fluoride 0.243%.....	<b>Purpose</b> Anticavity	<b>Directions</b> <b>Adults and children 2 years of age and older:</b> brush teeth thoroughly, preferably after each meal or at least twice per day, or as directed by a dentist or doctor. • <b>Instruct children under 6 years of age</b> in good brushing and rinsing habits (to minimize swallowing). • <b>Supervise children</b> as necessary until capable of using without supervision. • <b>Children under 2 years of age:</b> consult a dentist or doctor.	
<b>Uses</b> aids in the prevention of dental cavities		<b>Inactive ingredients</b> water, sorbitol, hydrated silica, disodium pyrophosphate, sodium lauryl sulfate, flavor, cellulose gum, xanthan gum, carbomer, sodium saccharin, sodium hydroxide, mica, titanium dioxide, blue 1 lake, polyethylene	
<b>Warnings</b> Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.		<b>Store in a cool, dry place. Keep tube capped when not in use.</b>	

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademarks Crest® and 3D White™.

**HyVee**

# Brilliant White

ANTI-CAVITY WHITENING TOOTHPASTE WITH FLUORIDE  
REMOVES SURFACE STAINS TO WHITEN TEETH  
Enamel safe formula

Compare to the active ingredient in Crest® 3D White™ Vivid\*

Cool Mint

NET WT 5.8 OZ (164 g)

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**HyVee**

Reveal a whiter, more radiant smile with HyVee® Brilliant White Toothpaste. HyVee® Brilliant White Toothpaste safely and gently removes surface stains from teeth while the gentle foaming action cleans hard to reach areas for a whiter, brighter smile.

- Mild foaming action helps clean hard to reach areas
- Helps strengthen enamel
- Fights plaque & cavities
- Freshens breath

DISTRIBUTED BY HY-VEE, INC., WEST DES MOINES, IA 50266  
SATISFACTION GUARANTEED CALL 1-800-289-8343  
www.hy-vee.com  
MADE IN USA

**FOR POSITION ONLY**  
0 75450 06272 4

Bend Line



Compare to the same active ingredient in Crest® 3D White™ Vivid\*

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## HYVEE BRILLIANT WHITE

fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:42507-197
<b>Route of Administration</b>	DENTAL	<b>DEA Schedule</b>	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	SODIUM FLUORIDE	0.243 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER	
SACCHARIN SODIUM	
SORBITOL	
TITANIUM DIOXIDE	
SODIUM HYDROXIDE	

XANTHAN GUM	
HYDRATED SILICA	
SODIUM ACID PYROPHOSPHATE	
CARBOXYMETHYLCELLULOSE SODIUM	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)	
SODIUM LAURYL SULFATE	
MICA	

Product Characteristics			
Color	blue (light blue with sparkles)	Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-197-79	1 in 1 CARTON		
1	NDC:42507-197-72	16.4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/20/2011	

**Labeler** - HyVee Inc (006925671)

**Registrant** - Lornamead (126440440)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(42507-197), pack(42507-197)