

**LUSTER NOW INSTANT WHITENING- sodium fluoride gel, dentifrice
DENTOVATIONS 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.

Luster Now Instant Whitening Toothpaste

ACTIVE INGREDIENT: SODIUM FLUORIDE 0.24% (W/W)

PURPOSE:

ANTI-CAVITY

USES: ANTI-CAVITY.

WARNINGS: IF MORE THAN THE AMOUNT USED FOR BRUSHING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY. AVOID CONTACT OF THE PRODUCT WITH THE EYE. IF IRRITATION (SUCH AS REDNESS, SWELLING, SORENESS) OF THE GUM OR THE MOUTH OCCURS, DISCONTINUE USE AND CONSULT A DENTIST.

KEEP OUT OF REACH OF CHILDREN UNDER 12 YEARS.

DIRECTIONS: ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER:

FOR THE BEST RESULTS BRUSH TEETH THOROUGHLY, PREFERABLY AFTER EACH MEAL OR AT LEAST TWICE A DAY, OR AS DIRECTED BY A DENTIST OR DOCTOR. DO NOT SWALLOW. PRODUCT IS NOT RECOMMENDED FOR USE BY CHILDREN UNDER 12 YEARS OF AGE.

OTHER INFORMATION: STORE BETWEEN 59-80°F (15-27°C).

INACTIVE INGREDIENTS: Sorbitol, Silica, Water, Propylene Glycol, Sodium Lauryl Sulfate, Flavor, Disodium Phosphate, PVM/MA Copolymer,

Cellulose Gum, Sodium Benzoate, Potassium Acesulfame, Xanthan Gum, Tetrasodium Pyrophosphate, Titanium Dioxide, FD&C Blue No. 1

QUESTIONS OR COMMENTS?

1-800-823-5272 * M-F 9 A.M. - 5 P.M. EST * LUSTERPREMIUMWHITE.COM

ACTIVE (MEDICINAL) INGREDIENT/INGRÉDIENT ACTIF (MÉDICAMENTEUX) : Sodium Fluoride 0.24% (w/w)/fluorure de sodium 0.24% (w/w) **PURPOSE:** Anticavity **WARNINGS:** Keep out of reach of children under 12 years of age. If more than amount used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. If irritation (such as redness, swelling, soreness) of the gums or the mouth occurs, discontinue use and consult a dentist. **DIRECTIONS:** Adults and Children 12 years of age and older: Brush teeth thoroughly, preferably after each meal, minimum twice daily, or as directed by a dentist or health care practitioner. Do not swallow. Product is not recommended for use by children under 12 years.

INACTIVE (NON-MEDICINAL) INGREDIENTS/INGRÉDIENTS INACTIFS (NON MÉDICAMENTEUX) : Sorbitol, Silica, Water/Eau, Propylene Glycol, Sodium Lauryl Sulfate, Flavor/Aroma, Disodium Phosphate, PVM/MA Copolymer, Cellulose Gum, Sodium Benzozate, Potassium Acesulfame, Xanthan Gum, Tetrasodium Pyrophosphate, Titanium Dioxide, FD&C Blue No. 1 (CI 42090) **EMPLI :** Produit anticarie **AVERTISSEMENTS :** Garder hors de la portée des enfants de moins de 12 ans. Si l'exécédent de dentifrice est accidentellement avalé pendant le brossage des dents, obtenir de l'aide médicale ou contacter un centre antipoison immédiatement. En cas d'irritation (telle que de la rougeur, de l'enflure ou de la douleur) des gencives ou de la bouche, cesser d'utiliser le produit et consulter un dentiste. **MODE D'EMPLOI :** Adultes et enfants de 12 ans et plus : Brosser les dents à fond, préférentiellement après chaque repas ou au moins deux fois par jour ou tel que prescrit par un dentiste. Ne pas avaler. Le produit n'est pas recommandé pour les enfants de moins de 12 ans.

Manufactured for/Fabrique pour : Dentovations Inc. Boston, MA 02210. In Canada imported by/importé au Canada par : Dentovations, Inc. Brampton, L7A 3W5, Canada. MADE IN USA. FABRIQUE AUX E.-U.
QUESTIONS? 1-800-823-5272 M-F 9 a.m. - 5 p.m. EST L-V 9 h - 17 h HNE LusterPremiumWhite.com



LUSTER NOW!

INSTANT WHITENING TOOTHPASTE

Anti-Cavity Fluoride Toothpaste

DENTIFRICE BLANCHIMENT INSTANTANÉ

Dentifrice au fluorure anticarie

HAPPY MINT FLAVOR SAVEUR MENTHE JOYEUSE

NPN 80039777

NET WT./POIDS NET 4 oz (113 g)

LUSTER NOW INSTANT WHITENING

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57353-103
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57353-103-53	1 in 1 BOX	06/20/2016	
1	NDC:57353-103-13	113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:57353-103-31	3 in 1 BOX	06/20/2016	
2	NDC:57353-103-11	42 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 final	part355	12/01/2012	

Labeler - DENTOVATIONS INC (128248676)

Registrant - Lornamead Inc. (078584069)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		078584069	manufacture(57353-103)