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


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Boston, MA 02210. Made in the USA
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HAPPY MINT FLAVOR
NET WT. 4 oz (113 g)
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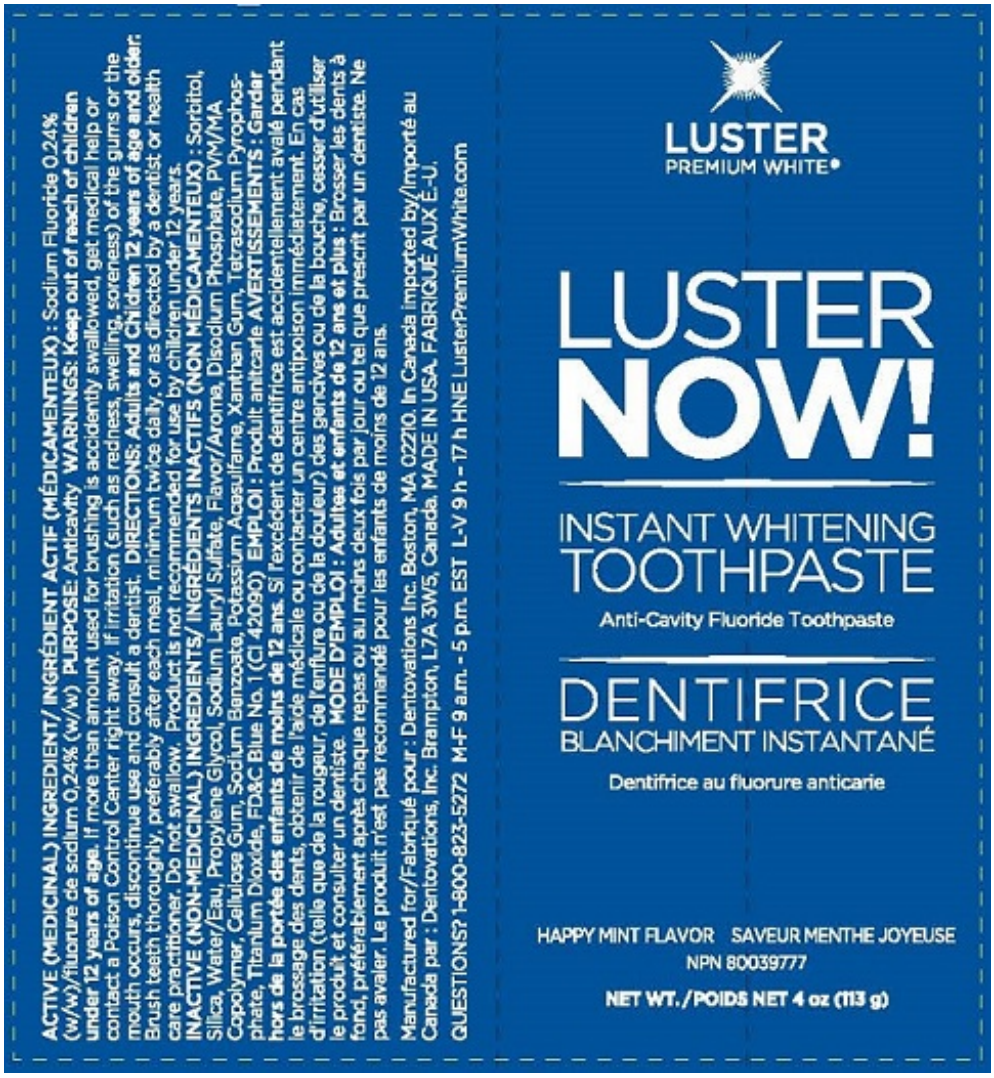

LUSTER NOW INSTANT WHITENING

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: 059QF0KO0R)	
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: H3R47K3TBD)	

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)

Revised: 2/2019 DENTOVATIONS INC