

**LUSTER PREMIUM WHITE- sodium fluoride gel, dentifrice**  
**French Transit, Ltd**

*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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**LUSTER PREMIUM WHITE PEARL**

**ACTIVE INGREDIENT**

SODIUM FLUORIDE 0.24% (0.15% W/V FLUORIDE ION)

**PURPOSE**

ANTICAVITY

**USE**

HELPS PROTECT AGAINST CAVITIES.

**WARNINGS**

If you accidentally swallow more than used for brushing, get medical help,  
Keep out of reach of children under 6 years of age.

**DIRECTIONS**

- Adults and children 6 years of age and older—Brush teeth thoroughly, preferably after each meal, at least twice daily, or as directed by dentist or doctor.
- Children 6 to 12 years—Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 6 years—Do not use unless directed by dentist or physician.

**INACTIVE INGREDIENTS**

Sorbitol, Hydrated Silica, Water, Propylene Glycol, Sodium Lauroyl Sarcosinate, Flavor, Pvm/Ma Copolymer, Disodium Phosphate, Mica, Cellulose Gum, Sodium Benzoate, Potassium Acesulfame, Titanium Dioxide, Xanthan Gum, Tetrasodium Pyrophosphate, Hydrolyzed Pearl

**QUESTIONS**

1-800-823-5272 | French Transit, Ltd., Louisville, CO 80027 USA

\*Visit [LusterPremiumWhite.com](http://LusterPremiumWhite.com) for more information.



**LUSTER**  
PREMIUM WHITE®  
**PEARL**

NET WT 4 OZ (113 G)

WHITENING  
**PEARL INFUSED**  
TOOTHPASTE

Deep Cleans + Removes Stains\*

MINT



**Drug Facts**

**Active ingredient**  
Sodium Fluoride 0.24% (0.15% w/v fluoride ion) ----- **Purpose**  
Anticavity

**Use**  
Helps protect against cavities.

**Warnings**  
Keep out of reach of children under 6 years of age.  
If you accidentally swallow more than used for brushing, get medical help, or contact a Poison Control Center immediately.

**Directions** ■ Adults and children 6 years of age and older—Brush teeth thoroughly, preferably after each meal, at least twice daily, or as directed by a dentist or doctor. ■ Children 6 to 12 years—Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. ■ Children under 6 years—*Do not use unless directed by dentist or physician.*

**Inactive ingredients** Sorbitol, Hydrated Silica, Water, Propylene Glycol, Sodium Lauryl Sarcosinate, Flavor, Pvm/Ma Copolymer, Disodium Phosphate, Mica, Cellulose Gum, Sodium Benzoate, Potassium Acesulfame, Titanium Dioxide, Xanthan Gum, Tetrasodium Pyrophosphate, Hydrolyzed Pearl

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WHITENING  
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MINT  
NET WT 4 OZ (113 G)

**BRIGHTER  
BENEFITS**



WHITENS TEETH



FIGHTS CAVITIES



FRESHENS BREATH



**MADE WITHOUT:**  
Triclosan, Parabens,  
SLS/Sulfates



**NO TOOTH  
SENSITIVITY**

**LUSTER PREMIUM WHITE**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72805-102
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	.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 LAUROYL SARCO SINATE (UNII: 632GS99618)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
SODIUM PHOSPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
MICA (UNII: V8A1AW0880)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM ACETATE (UNII: M911911U02)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-102-14	1 in 1 BOX	10/23/2020	
1		113 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	10/23/2020	

**Labeler** - French Transit, Ltd (100044380)

Revised: 10/2020

French Transit, Ltd