

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.

LUSTER PREMIUM WHITE

ACTIVE INGREDIENT

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

PURPOSE

ANTI-CAVITY

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

Glycerin, Sorbitol, Hydrated Silica, Water (Aqua), Xylitol, Cocamidopropyl Betaine, Xanthan Gum, Mentha Piperita (Peppermint) Oil, Stevia Rebaudiana Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Mica, Titanium Dioxide, Charcoal Powder, Mentha Arvensis (Cornmint) Leaf Oil, Menthol, Vanilla Planifolia Fruit Extract

QUESTIONS

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

*Visit LusterPremiumWhite.com for more information.



NET WT 4 OZ (113 G)

ACTIVATED
WHITE CHARCOAL
 TOOTHPASTE

Charcoal Whitening with Zero Mess

MINT



Drug Facts

Active ingredient
 Sodium Fluoride 0.24% (0.15% w/w 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.*

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**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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-201
Route of Administration	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
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
TEA TREE OIL (UNII: VIF565UC2G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	
MENTHOL (UNII: L7T10EIP3A)	
VANILLA BEAN (UNII: Q74T35078H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-201-14	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.