

LUSTER PREMIUM WHITE AM/PM- sodium fluoride and sodium monofluorophosphate
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®
AM/PM

AM TOOTHPASTE

Drug Facts

Active ingredient

Sodium Fluoride 0.24% (w/w)

Purpose

Anticavity

Use

Helps protect against cavities.

Warnings

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.

Directions

Adults and children 6 years of age and older	Brush teeth thoroughly, preferably after each meal, at least once daily in the morning, 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 a dentist or physician.

Other information

Store between 10-27°C (50-80°F)

Inactive ingredients

Sorbitol, Silica, Water, Propylene Glycol, Sodium Lauroyl Sarcosinate, Flavor, Disodium Phosphate, PVM/MA Copolymer, Cellulose Gum, Sodium Benzoate, Potassium Acesulfame, Xanthan Gum, Tetrasodium Pyrophosphate, Titanium Dioxide, FD&C Blue No. 1

PM TOOTHPASTE

Drug Facts

Active ingredient

Sodium Monofluorophosphate 0.88% (w/w)

Purpose

Anticavity

Use

Helps protect against cavities.

Warnings

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.

Directions

Adults and children 6 years of age and older	Brush teeth thoroughly, preferably after each meal, at least once daily at night, or as directed by a dentist or doctor.
Children 6 to 12	Instruct in good brushing and rinsing habits (to minimize swallowing).

years	Supervise children as necessary until capable of using without supervision.
Children under 6 years	Do not use unless directed by a dentist or physician.

Other information

Store between 10-27°C (50-80°F)

Inactive Ingredients

Vegetable Glycerin, Calcium Pyrophosphate, Zea Mays (Corn) Starch, Propylene Glycol, PEG-12, Water, Hydrogen Peroxide, Sodium Lauroyl Sarcosinate, Flavor, Cellulose Gum, Carbomer, Sodium Saccharin, Butylated Hydroxytoluene

Questions?

1-800-823-5272

PRINCIPAL DISPLAY PANEL - Kit Carton

NEW!

LUSTER
PREMIUM WHITE®

AM | PM
TOOTHPASTE REINVENTED

3X WHITER IN 3 DAYS†

FRESHER BREATH

INSTANTLY WHITER TEETH

FIGHT CAVITIES

REMOVE DEEP STAINS

WHITEN INSIDE & OUT

STRONGER ENAMEL

PROVEN EFFECTIVE
PROFESSIONAL WHITENING TECHNOLOGY

ENAMEL SAFE / ZERO TOOTH SENSITIVITY

ANTICAVITY FLUORIDE TOOTHPASTE • MINT
AM NET WT. 4 OZ (113 g) | PM NET WT. 4 OZ (113 g)

SATISFACTION GUARANTEED‡



WHITEN LIKE A PRO™



AWARD-WINNING FORMULAS:

NEW!



WHITEN LIKE A PRO™

Luster AM/PM™ Toothpastes have been specially formulated to promote a healthier, whiter smile day and night.

AM | PM TOOTHPASTE REINVENTED

BRIGHTER BENEFITS:



SULFATE FREE



WHITENS SAFELY ABOVE & BELOW THE SURFACE



FIGHTS CAVITIES & BUILDS ENAMEL



CLEANS & FRESHENS BREATH

3X WHITER IN 3 DAYS*



FRESHER BREATH

INSTANTLY WHITER TEETH

FIGHT CAVITIES



REMOVE DEEP STAINS

WHITEN INSIDE & OUT

STRONGER ENAMEL

This proprietary formulation instantly counteracts yellowness to create an optical effect of whiter teeth that lasts for hours.

Enamel safe whitening, removes surface stains with daily use.

BRUSH WITH LUSTER PM TO: Put stubborn teeth stains to bed, with 2X MORE WHITENING POWER* that goes beyond surface stains to safely whiten above and below the tooth's surface.

Helps strengthen enamel with zero tooth sensitivity.

PROVEN EFFECTIVE PROFESSIONAL WHITENING TECHNOLOGY ENAMEL SAFE / ZERO TOOTH SENSITIVITY

ANTICAVITY FLUORIDE TOOTHPASTE - MINT AM NET WT. 4 OZ (113 g) | PM NET WT. 4 OZ (113 g)

* Up to 3X Whiter in 3 Days of brushing as directed, compared to brushing with regular toothpaste. Data on file. * Visit LusterPremiumWhite.com for more information. ** Compared to a leading fluoride toothpaste brand. Data on file.

AM TOOTHPASTE

Table with Drug Facts, Active ingredient (Sodium Fluoride 0.24%), Purpose (Anticavity), Use, Warnings, Directions, Other information, and Inactive ingredients for AM toothpaste.

PM TOOTHPASTE

Table with Drug Facts, Active ingredient (Sodium Monofluorophosphate 0.88%), Purpose (Anticavity), Use, Warnings, Directions, Other information, and Inactive ingredients for PM toothpaste.

Manufactured in the USA for: French Transit, Ltd., 398 Beach Rd., Burlingame, CA 94010, USA

W4082R1

5890715R1

SATISFACTION GUARANTEED†

MADE IN THE USA

SATISFACTION GUARANTEED†

MADE IN THE USA

289715R1



LUSTER PREMIUM WHITE AM/PM sodium fluoride and sodium monofluorophosphate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-120
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-120-13	1 in 1 CARTON	04/01/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	113 g
Part 2	1 TUBE	113 g

Part 1 of 2

AM

sodium fluoride paste

Product Information

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)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Lauroyl Sarcosinate (UNII: 632GS99618)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F)	
Carboxymethylcellulose Sodium, unspecified (UNII: K679OBS311)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Acesulfame Potassium (UNII: 23OV73Q5G9)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Xanthan Gum (UNII: TTV12P4NEE)	
Sodium Pyrophosphate (UNII: O352864B8Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		113 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	04/01/2018	

Part 2 of 2

PM

sodium monofluorophosphate paste

Product Information

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.88 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Calcium Pyrophosphate (UNII: X69NU20D19)	
Starch, Corn (UNII: O8232NY3SJ)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Polyethylene Glycol 600 (UNII: NL4J9F21N9)	
Hydrogen Peroxide (UNII: BBX060AN9V)	
Sodium Lauroyl Sarcosinate (UNII: 632GS99618)	
Carboxymethylcellulose Sodium, unspecified (UNII: K679OBS311)	
Carbomer Homopolymer Type A (Allyl Pentaerythritol Crosslinked) (UNII: F68VH75CJC)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	113 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	04/01/2018	

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OTC MONOGRAPH FINAL	part355	04/01/2018	

Labeler - French Transit, Ltd. (100044380)

Revised: 1/2022

French Transit, Ltd.