

THE BLUE TOOTHBRUSH- sodium fluoride gel, dentifrice
New-Light Co., 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.

ACTIVE INGREDIENT

Active ingredients: Sodium Fluoride 0.22%

INACTIVE INGREDIENT

Inactive ingredients:

D-Sorbitol solution, Concentrated Glycerin, Sodium Lauryl Sarcosinate, Peppermint oil, L-menthol, Methylparaben, Xylitol, Ascorbic acid, Tocopherol Acetate, Brilliant Blue FCF, Water

PURPOSE

Purpose: Aids in the prevention of dental decay

WARNINGS

Warnings: Supervise children using the toothbrush. Coated toothpaste is initial use, 'The Blue' toothbrush is reusable with toothpaste after initial use. Please change the toothbrush every 15days or when the bristles are worn out. Store in a cool place out of humidity and direct sunlight.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children: Keep out of the reach of children under 6 years of age.

INDICATIONS & USAGE

How to use: Use to remove the packaging and buried in a little water on the brush head.

DOSAGE & ADMINISTRATION

How to use: Use to remove the packaging and buried in a little water on the brush head.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Image of carton



Drug Facts

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NEW-LIGHT CO.,LTD

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The Blue toothbrush
Even without toothpaste?! No Problem with The Blue



The Blue for Travel
Going on a trip?
Just take The Blue toothbrush with you!



The Blue for Camping
Take The Blue with you on camping
trips or any outdoor activities.



The Blue for Guest
The Blue is affordable for you to stock up!



The Blue is Convenient
after having Lunch box.

The Blue toothbrush
Even without toothpaste?! No Problem with The Blue

Multiple Action System

- Safely cleans
- Fights cavities
- Freshens breath
- Removes plaque

THE BLUE TOOTHBRUSH

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69370-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0002 g in 25

Inactive Ingredients

Ingredient Name		Strength		
PEPPERMINT OIL (UNII: AV092KU4JH)				
XYLITOL (UNII: VCQ006KQ1E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69370-010-01	25 in 1 CARTON		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	12/01/2014		

Labeler - New-Light Co., Ltd (687405006)

Registrant - New-Light Co., Ltd (687405006)

Establishment

Name	Address	ID/FEI	Business Operations
New-Light Co., Ltd		687405006	manufacture(69370-010)

Revised: 1/2015

New-Light Co., Ltd