

**THE WHITE 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.*

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**ACTIVE INGREDIENT**

Active ingredient: 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 15 days 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.

**How to use**

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

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**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Image of carton



## THE WHITE TOOTHBRUSH

sodium fluoride gel, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69370-020
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Sodium Fluoride</b> (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:69370-020-01	25 in 1 CARTON		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/02/2015	

**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(69370-020)

Revised: 2/2015

New-Light Co., Ltd