

SUPERSMILE PROFESSIONAL WHITENING- fluoride paste, dentifrice
ROBELL RESEARCH, INC.

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.

Drug Facts

Active Ingredient:

Sodium Monofluorophosphate (0.14% w/v Fluoride Ion)

Purpose:

Anticavity toothpaste

Uses:

Aids in the prevention of dental cavities.

Warnings:

As with all fluoride toothpastes,
children under 6 years old.

Directions:

For best results: Brush teeth thoroughly after each meal, at least twice a day, or as directed by a dentist.

Directions:

Instruct children under six about good brushing and rinsing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision. Under two years of age consult a dentist or a doctor before use.

Inactive Ingredients:

Water, Sorbitol, Dicalcium Phosphate Dihydrate, Sodium Bicarbonate, Calcium Carbonate, Titanium Dioxide, Cellulose Gum, Calprox®, Sodium Perborate, Flavor, Corn Starch, Magnesium Carbonate, Sodium Lauryl Sulfoacetate, Methyl Paraben, Sodium Saccharin, Propyl Paraben

Questions:

1-800 -784 -SMILE

Tube Label

supersmile®

professional
whitening
toothpaste

Contains fluoride.
8 oz / 227 g

ICY MINT



Created by,
DR. IRWIN SMIGEL
World Renowned
Father of Aesthetic
Dentistry

For best results, place a pearl size drop of Whitening Toothpaste on a **DRY** toothbrush and brush in a circular motion for two minutes twice daily.

Whitens - Calprox® safely lifts surface stains, maintains and enhances the vibrancy of professionally bleached teeth, and restores bonding, caps, veneers and dentures to their original whiteness.

Freshens - Kills germs for long-lasting fresh breath.

Protects - Fluoride prevents cavities.

Safely - No harsh abrasives, no sensitivity.

Drug Facts

Active Ingredient: Sodium Monofluorophosphate
(0.14% w/v Fluoride Ion)

Purpose: Anticavity toothpaste

Uses: Aids in the prevention of dental cavities.

Warnings: As with all fluoride toothpastes, keep out of reach of children under 6 years old.

If you accidentally swallow more than used for brushing, get medical help or call a Poison Control Center right away.

Directions: For best results: Brush teeth thoroughly after each meal, at least twice a day, or as directed by a dentist. Instruct children under six about good brushing and rinsing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision. Under two years of age consult a dentist or a doctor before use.

Inactive Ingredients: Water, Sorbitol, Dicalcium Phosphate Dihydrate, Sodium Bicarbonate, Calcium Carbonate, Titanium Dioxide, Cellulose Gum, Calprox®, Sodium Perborate, Flavor, Corn Starch, Magnesium Carbonate, Sodium Lauryl Sulfosuccinate, Methyl Paraben, Sodium Saccharin, Propyl Paraben

Questions? 1-800-784-SMILE

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SUPERSMILE PROFESSIONAL WHITENING

fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53567-0101
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CALCIUM PEROXIDE (UNII: 7FRO2ENO91)	
SODIUM PERBORATE (UNII: Y52BK1W96C)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN (UNII: FST467XS7D)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53567-0101-6	227 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/28/2011	

Labeler - ROBELL RESEARCH, INC. (155571656)

Registrant - Lornamead (126440440)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(53567-0101) , pack(53567-0101)

Revised: 10/2012

ROBELL RESEARCH, INC.