

BRIGHT SMILES- sodium monofluorophosphate paste, dentifrice

Brooke Supplies

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.

Bright Smiles

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)

Purpose

Anticavity toothpaste

Use

aids in the prevention of dental cavities

Warning

Keep out of the 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 immediately.

Directions

- do not swallow
- supervise children as necessary until capable of using without supervision
- Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing).
- Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a doctor.
- Children under 6 years of age: Do not use unless directed by a doctor or dentist

Inactive ingredients

calcium carbonate, water, sorbitol, hydrated silica, sodium lauryl sulfate, sodium carboxymethyl cellulose, flavor, sodium saccharin, sodium methyl paraben, sodium propyl paraben.

PRINCIPAL DISPLAY PANEL - 42 g Tube Label

BrightSmiles

Fluoride Toothpaste

NET WT. 1.5 oz (42g)



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Drug Facts		Drug Facts (continued)
Active ingredient Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion).....	Purpose Anticavity toothpaste	<ul style="list-style-type: none"> • Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). • Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a doctor. • Children under 6 years of age: Do not use unless directed by a doctor or dentist
Use aids in the prevention of dental cavities		
Warning Keep out of the 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 immediately.		
Directions • do not swallow • supervise children as necessary until capable of using without supervision ▶		Inactive ingredients calcium carbonate, water, sorbitol, hydrated silica, sodium lauryl sulfate, sodium carboxymethyl cellulose, flavor, sodium saccharin, sodium methyl paraben, sodium propyl paraben.



Exclusive Distributor:  BrookeSupplies 525 E. County Line Road Lakewood, NJ 08701
 Made in India. Mfg. date & Batch No. on Crimp. Exp. date: 3 yrs from date of Mfg.

BRIGHT SMILES

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71074-108
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)

PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71074-108-37	17 g in 1 TUBE; Type 0: Not a Combination Product	05/15/2016	
2	NDC:71074-108-38	24 g in 1 TUBE; Type 0: Not a Combination Product	05/15/2016	
3	NDC:71074-108-39	42 g in 1 TUBE; Type 0: Not a Combination Product	05/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	05/15/2016	

Labeler - Brooke Supplies (034574770)

Establishment

Name	Address	ID/FEI	Business Operations
SKYLARK CMC PVT. LTD.		650174824	MANUFACTURE(71074-108)

Revised: 1/2017

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