

BRIGHT SMILES- sodium fluoride gel, 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 Fluoride 0.22%
(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 2 years of age: Consult a dentist doctor.

Inactive ingredients

sorbitol, water, 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 Gel Toothpaste

NET WT. 1.5 oz (42g)

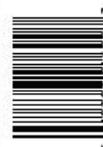


BrightSmiles

Fluoride *Gel* Toothpaste

NET WT. 1.5 oz (42g)

| Drug Facts | | Drug Facts (continued) |
|--|---|---|
| Active Ingredient Sodium Fluoride 0.22% (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 2 years of age: Consult a dentist doctor. |
| 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. | | Inactive ingredients sorbitol, water, hydrated silica, sodium lauryl sulfate, sodium carboxymethyl cellulose, flavor, sodium saccharin, sodium methyl paraben, sodium propyl paraben. |
| Directions • do not swallow • supervise children as necessary until capable of using without supervision ▶ | | |



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 fluoride gel, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71074-109 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O) | Fluoride Ion | 0.1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |
| 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:71074-109-41 | 7.9 g in 1 TUBE; Type 0: Not a Combination Product | 05/15/2016 | |
| 2 | NDC:71074-109-42 | 17 g in 1 TUBE; Type 0: Not a Combination Product | 05/15/2016 | |
| 3 | NDC:71074-109-43 | 24 g in 1 TUBE; Type 0: Not a Combination Product | 05/15/2016 | |
| 4 | NDC:71074-109-44 | 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(71074-109) |

Revised: 1/2017

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