

BARBIE- sodium monofluorophosphate paste, dentifrice
Ashtel Studios, 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.

Barbie Anticavity Fluoride Toothpaste

Drug Facts

Active Ingredients

Sodium Monofluorophosphate 0.76%

Purpose

Anticavity Toothpaste

Uses

Helps protect teeth and roots against cavities.

Warning

If more than used for brushing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

KEEP OUT OF REACH OF CHILDREN.

Directions

Adults and children 2 years of age and older:

- Brush teeth thoroughly after meals or at least twice a day. Use as directed by a dentist.
- Do not swallow.
- To minimize swallowing, use a pea-sized amount in children under 6 years of age.
- Supervise children's brushing until good brushing habit are established.
- Children under 2 years of age: Ask a dentist.

Inactive Ingredients

Sorbitol, Water, Silica, Sodium Lauryl Sulfate, Xylitol, Flavor, CMC Sodium Carboxymethyl Cellulose, Sodium Benzoate, Xanthan Gum, Saccharin Sodium, Rose Red

Other Information

Store at room temperature.

BUBBLE GUM FLAVOR

HELPS PREVENT CAVITIES!

ANTICAVITY FLUORIDE TOOTHPASTE

Alcohol & Sugar Free

QUESTIONS OR COMMENTS?

1-877-274-8358 (U.S.A.)

1-909-434-0911 (INTERNATIONAL)

ONTARIO, CA 91761

DESIGNED IN U.S.A.

MADE IN CHINA

DISTRIBUTED BY ASHTEL STUDIOS INC.

Packaging

Brush Buddies
Barbie
BUBBLE GUM FLAVOR
HELPS PREVENT CAVITIES!
ANTICAVITY FLUORIDE TOOTHPASTE
4.2 oz (119 g)
Alcohol & Sugar Free

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Brush Buddies
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1-877-274-8154 (U.S.A.)
1-800-454-0911 (INTERNATIONAL)
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Item # 00729-24

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BARBIE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70 108-016

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| 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 | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | | |
| ROSE BENGAL SODIUM (UNII: 956575SN5L) | | | | |
| Product Characteristics | | | | |
| Color | | Score | | |
| Shape | | Size | | |
| Flavor | BUBBLE GUM | Imprint Code | | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70108-016-01 | 119 g in 1 TUBE; Type 0: Not a Combination Product | 07/25/2018 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part355 | 07/25/2018 | | |

Labeler - Ashtel Studios, Inc. (148689180)