COLGATE KIDS WONDER WOMAN ALCOHOL FREE ANTICAVITY BUBBLE FRUITsodium fluoride rinse

Colgate-Palmolive Company

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.

Colgate[®] Kids Wonder Woman Alcohol Free Anticavity Mouthwash Bubble Fruit[®] Drug Facts

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older:

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

Other information

Store at controlled room temperature $68 - 77^{\circ}$ F $(20 - 25^{\circ}$ C)

Inactive ingredients

water, glycerin, propylene glycol, sorbitol, poloxamer 338, poloxamer 407, flavor, PEG-40 castor oil, phosphoric acid, sodium saccharin, disodium phosphate, potassium sorbate, cetylpyridinium chloride, sucralose, blue 1

Questions?

1-800-468-6502

Dist. by: COLGATE-PALMOLIVE CO. New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 250 mL Bottle Label

ALCOHOL FREE

Colgate®

Kids

Anticavity Fluoride Rinse

8.4 FL OZ (250 mL)

- StrengthensEnamel
- Protects from Cavities
- Cleans the Whole Mouth*

Paradise Island BUBBLE FRUIT®

P9927916

IMPORTANT: Read directions for proper use





sodium fluoride rinse

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:35000-333 |
| 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 mg in 1 mL | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | |
| CETYLPYRIDINIUM CHLO RIDE (UNII: D9 O M4SK49 P) | | |
| SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY) | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | | |
| POLOXAMER 338 (UNII: F75JV2T505) | | |
| SODIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F) | | |
| PEG-40 CASTOR OIL (UNII: 4ERD2076EF) | | |
| PHO SPHORIC ACID (UNII: E4GA8884NN) | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | BLUE | Score | |
| Shape | | Size | |
| Flavor | FRUIT | Imprint Code | |
| Contains | | | |

|] | Packaging | | | |
|---|------------------|---|-----------------------------|---------------------------|
| 7 | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| : | NDC:35000-333-84 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/28/2019 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL | part355 | 06/28/2019 | |
| | | | |

Labeler - Colgate-Palmolive Company (001344381)

| Establishment | | | | |
|-------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Colgate-Palmolive | | 785047999 | MANUFACTURE(35000-333) | |

Revised: 12/2019 Colgate-Palmolive Company