

**COLGATE KIDS BATMAN ALCOHOL FREE ANTICAVITY MOUTHWASH BAT-SIGNAL BUBBLE FRUIT- sodium fluoride rinse**

**Colgate-Palmolive**

*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.*

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**Colgate® Kids Batman Alcohol Free Anticavity Mouthwash Bat-Signal 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° F (20 – 25°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)

- ☐ Strengthens  
Enamel
- ☐ Protects from  
Cavities
- ☐ Cleans the  
Whole Mouth\*

Bat-Signal BUBBLE FRUIT®

**IMPORTANT:** Read directions for proper use

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ALCOHOL FREE

# Colgate®

Anticavity Fluoride Rinse

## Kids



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(250 mL)

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**Bat-Signal BUBBLE FRUIT®**

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**Does Not Contain Ethanol**

\*Swishes away particles brushing may miss

**CAP SEALED WITH PRINTED BAND**

**To Open: Remove printed band; squeeze cap and turn. To Close: Turn cap until it clicks.**

[www.colgate.com/kids](http://www.colgate.com/kids)

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

BATMAN and all related characters and elements © & ™ DC Comics.  
WB SHIELD © & ™ WBB. (S18)



**SAVE WATER**

[www.colgate.com/savewater](http://www.colgate.com/savewater)

smartlabel™

visit [smartlabel.colgate.com](http://smartlabel.colgate.com) for ingredient information

**GLUTEN FREE**





# COLGATE KIDS BATMAN ALCOHOL FREE ANTICAVITY MOUTHWASH BAT-SIGNAL BUBBLE FRUIT

sodium fluoride rinse

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:35000-332 |
| 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 CHLORIDE (UNII: D9OM4SK49P)             |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                     |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                            |          |
| POLOXAMER 407 (UNII: TUF2IVW3M2)                        |          |
| POLOXAMER 338 (UNII: F75JV2T505)                        |          |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) |          |
| PEG-40 CASTOR OIL (UNII: 4ERD2076EF)                    |          |
| PHOSPHORIC ACID (UNII: E4GA8884NN)                      |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                      |          |

## Product Characteristics

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

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:35000-332-84 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/28/2019           |                    |
| 2 | NDC:35000-332-52 | 500 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 (001344381)

## Establishment

| Name              | Address | ID/FEI    | Business Operations    |
|-------------------|---------|-----------|------------------------|
| Colgate-Palmolive |         | 785047999 | MANUFACTURE(35000-332) |

Revised: 12/2019

Colgate-Palmolive