

COLGATE CAVITY PROTECTION FRESH CLEAN- sodium fluoride mouthwash

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® Cavity Protection Fresh Clean

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 407, Poloxamer 338, PEG-40 Hydrogenated Castor Oil, Phosphoric Acid, Sodium Saccharin, Flavor, Disodium Phosphate, Potassium Sorbate, Cetylpyridinium Chloride, Sucralose, Green 3, Yellow 6.

Questions?

1-800-468-6502

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

PRINCIPAL DISPLAY PANEL - 225 mL Bottle Label

Colgate®
Anticavity Fluoride Mouthwash

FRESH
+
CLEAN

Freshens breath
Strengthens enamel

IMPORTANT:
Read directions
for proper use

FRESH
MINT

7.6 FL OZ (225 mL)

P9936694



FRESH + CLEAN

Freshens breath
Strengthens enamel



IMPORTANT:
Read directions
for proper use

FRESH
MINT

7.6 FL OZ (225 mL)

P9936894



Drug Facts

| Active ingredient | Purpose |
|---|------------|
| Sodium Fluoride 0.02% (0.01% w/v fluoride ion)..... | Anticavity |

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Does Not Contain Ethanol
CAP SEALED WITH PRINTED BAND

To Open: Remove printed band; squeeze cap and turn.

Turn cap until it clicks.

P9937078



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



COLGATE CAVITY PROTECTION FRESH CLEAN

sodium fluoride mouthwash

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:35000-884 |
| 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) |
| POLOXAMER 407 (UNII: TUF2IVW3M2) |
| POLOXAMER 338 (UNII: F75JV2T505) |
| PEG-40 CASTOR OIL (UNII: 4ERD2076EF) |
| PHOSPHORIC ACID (UNII: E4GA8884NN) |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) |
| CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) |
| SUCRALOSE (UNII: 96K6UQ3ZD4) |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) |

| Product Characteristics | | | |
|--------------------------------|-------|---------------------|--|
| Color | GREEN | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:35000-884-96 | 225 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/12/2019 | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL | part355 | 12/12/2019 | |

Labeler - Colgate-Palmolive Company (001344381)

| Establishment | | | |
|----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Colgate-Palmolive | | 785047999 | MANUFACTURE(35000-884) |