

**CLOSE UP FRESHENING WITH MOUTHWASH- sodium fluoride gel, dentifrice
Church & Dwight Co., 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.

CLOSE UP Freshening Gel

Active ingredients

Sodium fluoride (0.24%)

Purpose

Anticavity toothpaste

Use: Aids in the prevention of dental decay

Warnings

Keep out of 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 right away.

Directions do not swallow supervise children as necessary until capable of using without supervision

adults and children 2 years and older brush teeth thoroughly after meals or at least twice a day,

or use as directed by a dentist or physician

children under 6 years instruct in good brushing and rinsing habits (to minimize swallowing)

children under 2 years ask a dentist or physician

Inactive ingredients sorbitol, water, hydrated silica, PEG-8, sodium lauryl sulfate, SD alcohol 38-B, flavor, cellulose gum, sodium saccharin, red 33, red 40.

Questions or comments? Call 1-800-786-5135 Monday-Friday 9am-5pm ET

Principal Display Panel

Anticavity Fluoride Toothpaste

CLOSE UP

with

Ultra

Cinnamon

Flavor Blast

Cleans, Whitens and Freshens

NET WT. 6.0 OZ. (170g)

FRESHENING GEL

with Mouthwash



CLOSE UP FRESHENING WITH MOUTHWASH

sodium fluoride gel, dentifrice

Product Information

| | | | |
|-------------------------|----------------|--------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10 237-6 44 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|-----------------|---------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 2.4 mg in 1 g |
|---|-----------------|---------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| PEG-8 STEARATE (UNII: 2P9L47VI5E) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |

Product Characteristics

| | | | |
|----------|----------|--------------|--|
| Color | red | Score | |
| Shape | | Size | |
| Flavor | CINNAMON | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:10237-644-40 | 1 in 1 CARTON | 03/01/2001 | |
| 1 | | 113.4 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:10237-644-60 | 1 in 1 CARTON | 03/01/2001 | |
| 2 | | 170 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:10237-644-72 | 1 in 1 CARTON | 03/01/2001 | |
| 3 | | 204 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:10237-644-80 | 1 in 1 CARTON | 03/01/2001 | |
| 4 | | 226.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 03/01/2001 | |

Labeler - Church & Dwight Co., Inc. (001211952)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| Church & Dwight Co., Inc. | | 043690812 | manufacture(10237-644) |

