

**TRULY RADIANT WHITENING AND STRENGTHENING RINSE CLEAN AND FRESH-
sodium fluoride 0.02% liquid
Church & Dwight Canada Corp**

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.

DRUG FACTS Truly Radiant Whitening and Strengthening CLEAN AND FRESH Fluoride Rinse

Drug Facts Truly Radiant Fluoride Rinse

Active ingredient

Sodium Fluoride 0.02%

Purpose

Anticavity

Uses

Aids in the prevention of dental cavities

Warnings

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

Keep out of reach of children.

Directions

Adults and children 6 years of age and older

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10mL (2 teaspoons) of rinse between your teeth for a least 1 minue 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

- do not use if safety seal is broken or missing

Inactive ingredients water, sorbitol, glycerin, propylene glycol, polysorbate 20, poloxamer 407, tetrasodium pyrophosphate, sodium lauryl sulfate, sodium bicarbonate (baking soda), disodium pyrophosphate, flavor, xylitol, sodium saccharin, d&c green 5, d&c red 33

Questions or comments call us at **1-800-786-5135 M-F 9am-5pm ET** or visit our website at www.TrulyRadiant.com

Truly Radiant Whitening & Strengthening Fluoride Rinse

Alcohol Free

Truly Radiant

Whitening & Strengthening Fluoride Rinse

CLEAN & FRESH

WHITER SMILE IN JUST 5 DAYS*

Plus Micro-Cleaners & Lasting Freshness

- **PEROXIDE-FREE Whitening**
- Fights Cavities & Strengthens Enamel
- Cleans Where Brushing May Miss

CLEAN MINT

16 FL OZ (473 mL)

Label AHLBFB-00119-01.jpg



TRULY RADIANT WHITENING AND STRENGTHENING RINSE CLEAN AND FRESH

sodium fluoride 0.02% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62864-665
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM ACID PYROPHOSPHATE (UNII: H5WVD9LZUD)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
XYLITOL (UNII: VCQ006KQ1E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62864-665-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62864-665-08	237 mL in 1 BOTTLE; 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	10/02/2015	

Labeler - Church & Dwight Canada Corp (253933600)

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Canada Corp.		253933600	manufacture(62864-665)