

ORAJEL FLUORIDE- 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.

Orajel Anticavity

Sodium Fluoride (0.24%)

Anticavity Toothpaste

Use aids in the prevention of dental decay

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:

twist off cap and remove foil seal

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

sorbitol, water, hydrated silica, PEG-8, flavor, cellulose gum, sodium saccharin, sodium lauryl sulfate, blue 1

Questions or comments Call us at 800 952 5080 Monday through Friday 9 - 5 ET or visit our website at www.oraljel.com

Berry Divine

Orajel™

Anticavity

Fluoride

Toothpaste

Shimmer and Shine

NET WT. 4.2 OZ (119g)

Nickelodeon

Berry Divine

Orajel™

Anticavity Fluoride Toothpaste

Shimmer and Shine

NET WT
4.2 OZ
(119 g)

nielsen-elan.

Drug Facts

Active Ingredient Purpose
Sodium fluoride (0.24%) ... Anticavity toothpaste

Use aids in the prevention of dental decay

Warnings
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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, flavor, cellulose gum, sodium saccharin, sodium lauryl sulfate, blue 1

Questions or comments? Call us at 1-800-862-5888 M-F 9am-5pm ET or visit our website at www.orajel.com

Tamper Evident: Do not use if inner foil is torn, cut or missing.

Church & Dwight Co., Inc., Ewing, NJ 08628 USA
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ORAJEL FLUORIDE

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-763
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	BERRY (Berry Devine)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-763-42	119 g in 1 TUBE; Type 0: Not a Combination Product	12/10/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/10/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	MANUFACTURE(10237-763)