

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 Fluoride Toothpaste

Sodium Fluoride (0.24%)

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.

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.orajel.com

Bubble Berry

Orajel

Anticavity

Fluoride

Toothpaste

Disney

Elena

Avalor

NET WT 4.2 OZ (119g)

Bubble Berry



Anticavity Fluoride Toothpaste



NET WT 4.2 OZ (119 g)

Orajel™ Anticavity Fluoride Toothpaste cleans and provides effective cavity protection with a great-tasting formula.

Drug Facts

Active Ingredient Purpose Sodium fluoride (0.24%) 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 ■ twist off cap and remove foil seal ■ do not swallow ■ supervise children as necessary until capable of using without supervision

Table with 2 columns: Age Group and Instruction. Rows include adults and children 2 years and older, children under 6 years, and children under 2 years.

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

Questions or comments? Call us at 1-800-952-5080 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.

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ORAJEL FLUORIDE

sodium fluoride gel, dentifrice

Product Information

Table with 4 columns: Product Type, HUMAN OTC DRUG, Item Code (Source), NDC:10237-773, Route of Administration, DENTAL

Active Ingredient/Active Moiety

Table with 4 columns: Ingredient Name, Basis of Strength, Strength, SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O), FLUORIDE ION, 6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	BERRY (Bubble Berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-773-42	1 g in 1 TUBE; Type 0: Not a Combination Product	10/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/24/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	manufacture(10237-773)

Revised: 10/2017

Church & Dwight Co., Inc.