

**ORAJEL- 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%)

(0.15% w/v fluoride ion)

Anticavity

Aids in the prevention of dental decay

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.

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 (corn), Water, Hydrated Silica (mineral), Glycerin (vegetable), Cellulose Gum (tree pulp/cotton seed), Cocamidopropyl Betaine (coconut-derived), Stevia Rebaudiana Leaf Extract (stevia), Natural Flavor. All active ingredients are described in the format "ingredient name (source)".

Questions or comments? Call us at 1-800-952-5080 M-F 9am - 5pm ET or visit our website at **orajelkids.com**

JURASSIC WORLD

Stage

3

2-10 YEARS

Orajel™

kids

NATURALLY

SOURCED*

anti•cavity

TOOTHPASTE

fluoride

NATURAL

BERRY

BLAST

OUR

COMMITMENT

CERTIFIED RENEWABLE ENERGY

Green-e®

PROUD SUPPORTER OF

Arbor Day

Foundation®

PLASTIC

TUBE

how2recycle.info

SCAN ME

NET WT 4.2 OZ (119 g)



ORAJEL

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-775
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

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

WATER (UNII: 059QF0KO0R)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-775-42	119 g in 1 TUBE; Type 0: Not a Combination Product	07/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/20/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	manufacture(10237-775)

Revised: 2/2022

Church & Dwight Co., Inc.