ORAJEL KIDSTOOTHPASTE- sodium fluoride paste, 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 Mermaid and Unicorn Fluoride Toothpaste

Active ingredient

Sodium fluoride 0.24%

Purpose

Anticavity toothpaste

Use

aids in the prevention of dental decay

Warnings

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

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 of physician

Inactive ingredients

sorbitol, water, hydrated silica, PEG-8, flavor, cellulose gum, sodium saccharin, sodium

Questions or comments?

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

Warnings

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Principal Display Panel

Mixed Berry

Orajel

Anticavity

Fluoride

Toothpaste

magical unicorns OR mermaid

NET WT 4.2 OZ (119 g)





ORAJEL KIDSTOOTHPASTE

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-785
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		
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			
SORBITOL (UNII: 506T60A25R)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:10237-785- 42	119 g in 1 TUBE; Type 0: Not a Combination Product	01/15/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	11/01/2019	

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

Establishment					
Name	Address	ID/FEI	Business Operations		
Church & Dwight Co., Inc.		043690812	MANUFACTURE(10237-785)		

Revised: 1/2023 Church & Dwight Co., Inc.