

**ORAJEL KIDS MY WAY ANTICAVITY TOOTHPASTE- 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.

Drug Facts

Active ingredient

Sodium fluoride (0.24%)

Purpose

Anticavity toothpaste

Use aids in the prevention of dental decay

Warnings

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

Directions

- 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 doctor

Keep out of reach of children under 6 years of age.

Inactive ingredients sorbitol, water, hydrated silica, PEG-32, flavor, cellulose gum, sodium saccharin, sodium lauryl sulfate, blue 1.

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

Principal Display Carton OJKFC-32370-01

Orajel Kids

My Way

Anticavity Fluoride Toothpaste

Over 100 Stickers Inside

Decorate Your Toothpaste Your Way

Fruit Burst Flavor

WARNING:

CHOKING HAZARD-

Small parts. Not for children under 3 years.

Carton image

NEW WT 3 OZ (85g)



ORAJEL KIDS MY WAY ANTICAVITY TOOTHPASTE

sodium fluoride gel, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:10237-728

Route of Administration

DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
PEG-32 STEARATE (UNII: 33GX5WQC0M)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	FRUIT (FRUIT BURST FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-728-30	1 in 1 CARTON		
1		85 g in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/01/2011	

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

Name	Address	ID/FEI	Business Operations
Accupac, Inc.		071609663	manufacture