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 use as directed by a dentist or physician

brush teeth thoroughly after meals or at least twice a day, or

use as directed by a dentist or physicial children under 6 years

instruct in good brushing and rinsing habits (to minimize

swallowing)

children under 2 years ask a dentist or physician

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

Inactive ingredients sorbitol, water, hydrated silica, PEG-8, flavor, cellulose gum, sodium saccharin, sodium lauryl sulfate, red 33.

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

Principal Display Carton

Oraiel

4 plus years Kids

My Way

Anticavity Fluroide Toothpaste

Over 100 Stickers Inside Decorate Your Toothpaste Your Way

BERRY BLAST

Decorate Your

Toothpaste Your Way!!

NEW WT 4.2 OZ (119g)

Left Carton image

NOT FOR COLOR





Drug Facts

Active Ingredient

Purpose

Sodium fluoride (0.24%) Anticavity toothpaste USB aids in the prevention of dental decay

Warnings

Keep out of reach of children under 5 years of age.
If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions wide not swallow wisupervise children as necessary until capable of using without supervision

adults and children 2 years and older brush teath thoroughly after meals or at least twice a day, or use as directed by a dentist or physician

children under

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, red 33.

Questions or comments? Call us at 1-800-962-6000 M-F 9am-5pm ET or visit our website at www.crajelmyway.com

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Includes Over 100 Individual Stickers Inside!













Colors and artwork of stickers may vary

INSTRUCTIONS:

Apply stickers to dry. clean toothpaste tube body, smoothing out any air bubbles. Allow to dry for 30 minutes. Stickers are intended for permanent application to the tube and are not reusable after application.



BB



Right Carton image



ORAJEL KIDS MY WAY ANTICAVITY TOOTHPASTE

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-740
Route of Administration	DENTAL		

Active Ingredient/Active Moiety				
Ingredient Nam	1e	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8 ZYQ 1474W7) (FLUORID	E 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)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 OBS 311)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)		
D&C RED NO.33 (UNII: 9DBA0SBB0L)		

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:10237-740-42	1 in 1 CARTON		
1	119 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	0 2/0 1/20 12	

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

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

Revised: 3/2012 Church & Dwight Co., Inc.