ORAJEL PAW PATROL- 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 Paw Patrol Anticavity Fluoride Toothpaste and Spinbrush Combo Pack

Active ingredient

Sodium fluoride 0.24%

Purpose

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

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Directions

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- 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 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

Principal Display Panel

Bubble Berry

Orajel

Anticavity

Fluoride

Toothpaste

PAW PATROL

nickelodeon

NET WT

4.2 OZ

(119 g)



Kid's Spinbrush

+

Orajel

kids

PAWSOME

COMBO PACK

PAW

PATROL

nickelodeon

COMBO PACK CONTENTS:

ONE POWERED TOOTHBRUSH

ONE FLUORIDE TOOTHPASTE

NET WT. 4.2oz (119g)

ONE 3"x4" WATER TATTOO SHEET

ONE RINSE CUP



ORAJEL PAW PATROL

sodium fluoride paste, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10237-795

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		
HYDRATED SILICA (UNII: Y6O7T4G8P9)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			

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

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-795- 42	1 in 1 BOX	10/01/2020	
1		119 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	10/01/2020	

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

Establishment				
Name	Address	ID/FEI	Business Operations	

Church & Dwight Co., Inc.

043690812

MANUFACTURE(10237-795)

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