

**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

Sodium fluoride 0.24%

(0.15% w/v fluoride ion)

Anticavity toothpaste

aids in the prevention of dental decay

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.

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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), Natural Flavor, Cocamidopropyl Betaine (coconut-derived), Stevia Rebaudiana Leaf Extract (stevia). All inactive 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 www.orajelkids.com

nickelodeon™

PAW

PATROL

STAGE

3

2-10 YEARS

Orajel™

kids

NATURALLY

SOURCED*

anti · cavity

TOOTHPASTE

fluoride

NATURAL

FRUITY

BUBBLE

NET WT 4.2 OZ (119 g)

Drug Facts

Active Ingredient	Purpose
Sodium fluoride (0.24%), (0.15% w/v fluoride ion)	Anticavity

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.

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

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

Questions or comments? Call us at 1-800-952-5030 M-F 9am-5pm ET or visit our website at orajelkids.com

*Over 99% Naturally Sourced Ingredients
Temper Evident: Do not use if inner foil is torn, out or missing.
Made in U.S.A.
Manufactured For Church & Dwight Co., Inc., Ewing, NJ 08021
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ORAJEL PAW PATROL
sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-786
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
HYDRATED SILICA (UNII: Y607T4G8P9)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-786-42	119 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	

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(10237-786)