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

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

Bubbl Berry Orajel Anticavity Fluoride Toothpaste PAW PATROL nickelodeon NET WT

4.2 OZ

(119 g)



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 Stre			Strength		
SODIUM FLUORIDE (U	ION	6 mg in 1 g				
Inactive Ingredien	ts Ingredient Name			Strength		
HYDRATED SILICA (UN	•		C	Strengtn		
METHYL SALICYLATE						
CARBOXYMETHYLCELLULOSE SODIUM (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 GLY	C OL 400 (UNII: B697894SGQ)					
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketir	g End Dat		
1 NDC:10237-786-42	119 g in 1 TUBE; Type 0: Not a Combination Product	11/0 1/20 19				
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketi	ng End Date		
OTC monograph final	part355	11/01/2019		-		
O I G monograph imai						

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

Establishment							
Name	Address	ID/FEI	Business Operations				
Church & Dwight Co., Inc.		043690812	manufacture(10237-786)				

Revised: 5/2020

Church & Dwight Co., Inc.