

KANGAROOORALCARETOOTHPASTE- sodium fluoride paste

Kangaroo Oral Care, LLC

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.

Kanagaroo Toothbrush Kit

Active Ingredient

sodium fluoride 0.24%±0.14% w/v fluoride ion

Purpose

Anticavitytoothpaste

Use

helps aid in the prevention of dental cavities.

Warning

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

Adults and children 6 years of age and older:brush teeth thoroughly, after meals or at least twice a day or use as directed by a dentist.

do not swallow

to minimize swallowing use a pea-sized amount in children under 6

supervise children as necessary until capable of using without supervision

Inactive Ingredients

Keep out of reach of children under 6 years of age

Keep out of reach of children under 6 years of age



KANGAROO ORAL CARE TOOTHPASTE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72840-1901
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL, L- (UNII: 01Q0586BG1)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DISODIUM CARBOXYMETHYLARSONATE (UNII: T9HTL93NB7)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72840-1901-1	24 g in 1 KIT; Type 1: Convenience Kit of Co-Package	02/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/04/2019	

Labeler - Kangaroo Oral Care, LLC (081040249)

Registrant - Kangaroo Oral Care, LLC (081040249)

Establishment

Name	Address	ID/FEI	Business Operations
Kangaroo Oral Care, LLC		081040249	label(72840-1901)

Revised: 1/2019

Kangaroo Oral Care, LLC