

PRIYAL- sodium monofluorophosphate paste, dentifrice

Priyal Cosmetics

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.

Priyal Toothpaste

Active Ingredient

Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)

Purpose

Anticavity toothpaste

Uses

aids in the prevention of dental cavities

Warning

Keep out of the 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 immediately

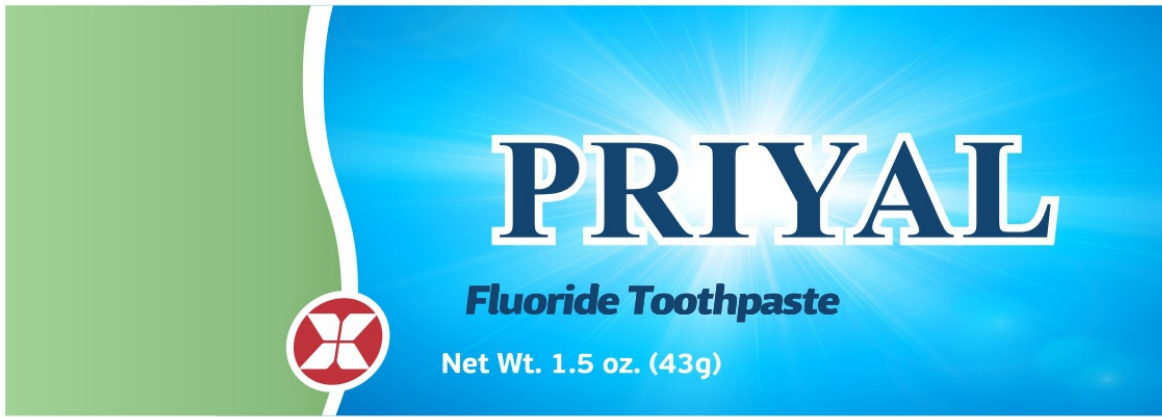
Directions

■ do not swallow ■ supervise children as necessary until capable of using without supervision ■ instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing) ■ adults and children 6 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor ■ children under 6 years of age: do not use unless directed by a doctor or dentist

Inactive ingredients

calcium carbonate, water, sorbitol, hydrated silica, sodium lauryl sulfate, sodium carboxymethyl cellulose, Flavor, sodium saccharin, sodium methylparaben, sodium propylparaben

Package Label



Manufactured by:
Priyal Cosmetics
167, Mahagujara Industrial Estate,
Moraiya, Near Changodar, Sarandi,
Ahmedabad-382213, Gujarat,
India

6U/C9/6C/31/1474

Drug Facts
Active Ingredient Purpose Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion).....Anticavity toothpaste
Use aids in the prevention of dental cavities
Warnings: Keep out of the 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 immediately
Directions: ■ Do not Swallow ■ Supervise children as necessary until capable of using without supervision ■ Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing) ■ Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician ■ Children under 6 years of age: Do not use unless directed by a dentist or physician
Other Information: ■ Store at 59° - 86°F (15° - 30°C) ■ Avoid excessive heat
Inactive Ingredients: Calcium Carbonate, Water, Sorbitol, Hydrated Silica, Sodium Lauryl Sulfate, Sodium Carboxymethyl Cellulose, Flavor, Sodium Saccharin, Sodium Methyl Paraben and Sodium Propyl Paraben

PRIYAL

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72822-900
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)	

PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72822-900-53	43 g in 1 TUBE; Type 0: Not a Combination Product	05/27/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/27/2013	

Labeler - Priyal Cosmetics (675482356)

Establishment

Name	Address	ID/FEI	Business Operations
Priyal Cosmetics		675482356	manufacture(72822-900)

Revised: 7/2020

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