

CINNAFRESH ANTICAVITY- sodium fluoride gel, dentifrice
Daxal Cosmetics Private Limited

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.

Cinnafresh AntiCavity Gel Toothpaste

ACTIVE INGREDIENT

Sodium Fluoride - 0.22% (0.1% w/v fluoride ion)

DRUG FACTS

PURPOSE

Anticavity Toothpaste.

USE

Helps protect against cavities.

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 immediately.

DIRECTIONS:

Adults & Children 6 years of age & older : Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

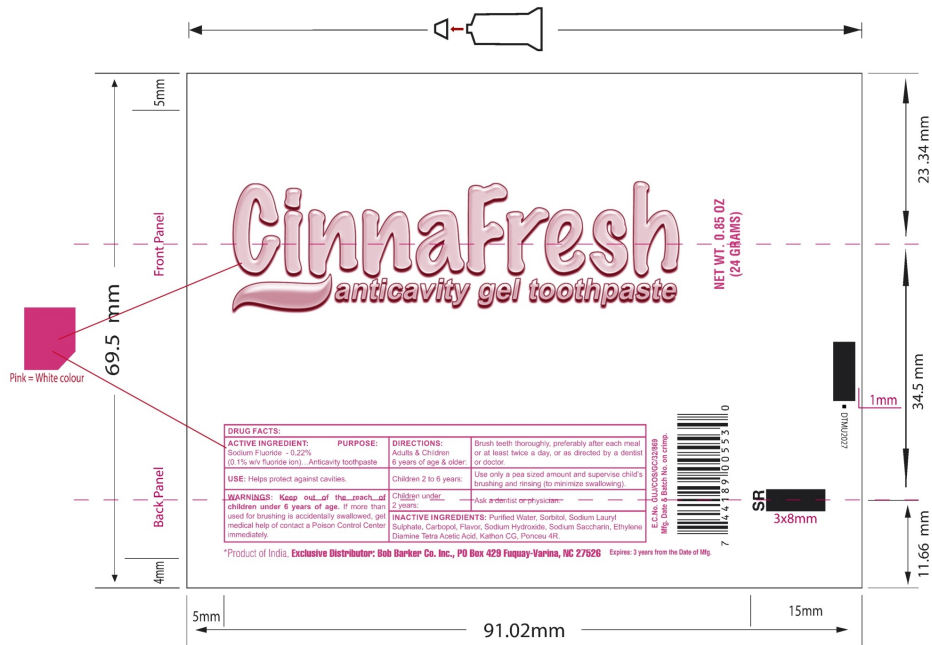
Children 2 to 6 years : Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).

Children under 2 years : Ask a dentist or physician.

INACTIVE INGREDIENTS:

Purified Water, Sorbitol, Sodium Lauryl Sulphate, Carbopol, Flavor, Sodium Hydroxide, Sodium Saccharin, Ethylene Diamine Tetra Acetic Acid, Kathon CG, Ponceu 4R.

PRINCIPAL DISPLAY PANEL - 24 g Tube



CINNAFRESH ANTICAVITY

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76001-003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYZ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PONCEAU 4R (UNII: Z525CBK9PG)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76001-003-01	24 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/01/2018	

Labeler - Daxal Cosmetics Private Limited (650497790)

Establishment

Name	Address	ID/FEI	Business Operations
Daxal Cosmetics Private Limited		650497790	manufacture(76001-003)

Revised: 8/2019

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