## CINNAFRESH- sodium fluoride gel, dentifrice Bob Barker Company 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.

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CinnaFresh®

**Drug Facts** 

## Active ingredient

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

### **Purpose**

Anticavity toothpaste

#### Use

Helps protect against 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**

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**

Water, Sorbitol, Sodium Lauryl Sulfate, Carbomer, Sodium Saccharin, PEG – 40 Hydrogenated Castor Oil, Sodium Hydroxide, Sodium Benzoate, Flavor, FD&C 40

Dist. by Bob Barker Co. Inc. Fuquay-Varina, NC 27526

#### PRINCIPAL DISPLAY PANEL - 24 GRAM Tube Label

CinnaFresh® anticavity gel toothpaste Sodium Fluoride 0.22% Bold Cinnamon Flavor

**NET WT. 0.85 OZ** 





E.C.No. GUJ/COS/GC/32/869 Mfg. Date & Batch No. on crimp.

Drug Facts	Drug Facts (continued)	
Active ingredient: Purpose: lodium Flueride - 0.22% 0.1% w/v flueride ion)Anticavity toothpaste	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.
Jse: Helps protect against cavities.	Children 2 to 6 years:	Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
Varnings:	Children under 2 years:	Ask a dentist or physician.
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## **CINNAFRESH**

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53247-120
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	2.2 mg in 1 g	

	Inactive Ingredients	
ı	Ingredient Name	Strength

Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
Sodium Hydroxide (UNII: 55X04QC32I)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
Sodium Benzoate (UNII: OJ245FE5EU)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:53247-120-01	24 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 0 8	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	0 1/0 1/20 0 8	

# Labeler - Bob Barker Company Inc. (058525536)

Revised: 11/2019 Bob Barker Company Inc.