CARDINAL HEALTH FLUORIDE ANTICAVITY- fluoride anticavity toothpaste paste, dentifrice
Cardinal Health

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.

Drug Facts:

NDC (63517-016-96)

Active Ingredient:

Sodium fluoride - 0.243% w/w

Purpose

Anticavity toothpaste

Uses:

- Aids in the prevention of dental decay

Warnings:

- If you accidentally swallow more than used for brushing ,seek medical help or contact a Poison Control Center right away.

Keep out of the reach of children under 6 years of age.

Directions:

- Adults and Children 2 years of age and older: Brush teeth thoroughly, after meals or at least twice a day, or as directed by a dentist or physician.
- Instruct children 6 years of age in good brushing and rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Chlidren under 2 years of age: Consult a dentist or physician.

Inactive ingredients:

Cellulose Gum, Flavor, Disodium Phosphate, and FD&C Blue No. 1, Glycerin, Hydrated Silica, PEG 6, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Titanium Dioxide, Water

Principal Display Panel - .85oz 144 count Box

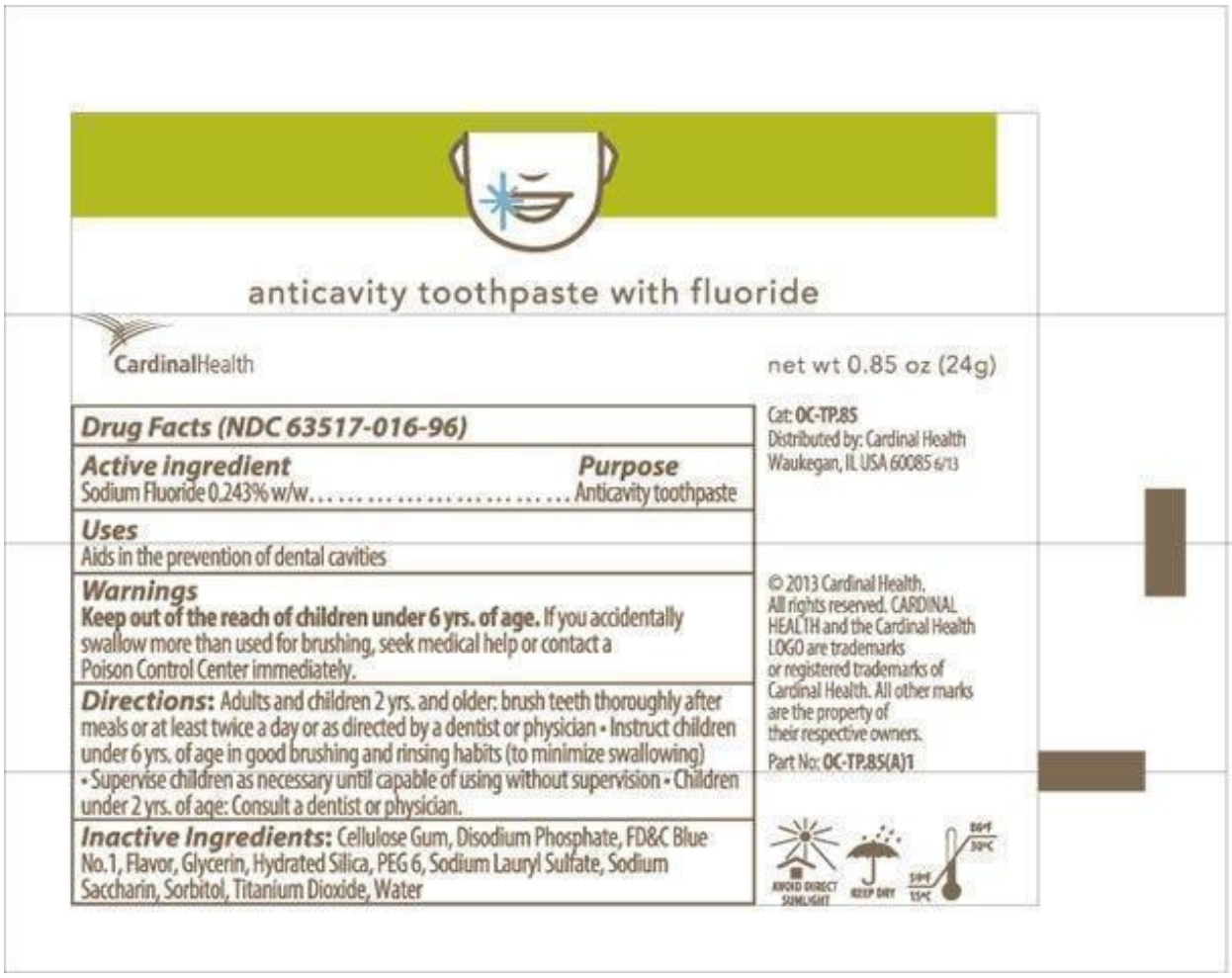
anticavity toothpaste with fluoride

ADA accepted

Principal Display Panel .85 oz -Tube

anticavity toothpaste with fluoride

Cardinal Health net wt. 0.85oz (24g)



CARDINAL HEALTH FLUORIDE ANTICAVITY

fluoride anticavity toothpaste paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63517-016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.43 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PEG-6 STEARATE (UNII: 8LQC57C6B0)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63517-016-96	144 in 1 CASE	09/09/2013	
1		24 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/09/2013	

Labeler - Cardinal Health (961027315)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(63517-016)