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)

anticavity toothpaste with fluc	oride
	inde
CardinalHealth	net wt 0.85 oz (24g)
Drug Facts (NDC 63517-016-96)	Cat: OC-TP:85 Distributed by: Cardinal Health
Active ingredient Purpose Sodium Fluoride 0.243% w/w	Waukegan, IL USA 60085 6/13
Uses Aids in the prevention of dental cavities	
Warnings Keep out of the reach of children under 6 yrs. of age. If you accidentally swallow more than used for brushing, seek medical help or contact a Poison Control Center immediately.	© 2013 Cardinal Health, All rights reserved, CARDINAL HEALTH and the Cardinal Health LOGO are trademarks or registered trademarks of
Directions: Adults and children 2 yrs, and older: brush teeth thoroughly after meals or at least twice a day or as directed by a dentist or physician - Instruct children under 6 yrs, of age in good brushing and rinsing habits (to minimize swallowing) - Supervise children as necessary until capable of using without supervision - Children under 2 yrs, of age: Consult a dentist or physician.	Cardinal Health. All other marks are the property of their respective owners. Part No: OC-TP.85(A)1
Inactive Ingredients: Cellulose Gum, Disodium Phosphate, FD&C Blue No.1, Flavor, Glycerin, Hydrated Silica, PEG 6, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Titanium Dioxide, Water	*~_/₩

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		

		ety				
	Ingredient Name				asis of Strength	Strength
SODIUM FLUORIDE (1	L UORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408			80) FL	UORIDE ION	2.43 mg in 1
Inactive Ingredie	nts					
		Ingredient N	Name			Strength
SORBITOL (UNII: 506	T60A25R)					
WATER (UNII: 059QF0	KO0R)					
HYDRATED SILICA (U	NII: Y6O7T4G8I	P9)				
GLYCERIN (UNII: PDC)	6A3C0OX)					
SODIUM LAURYL SUI	L FATE (UNII: 36	8GB5141J)				
PEG-6 STEARATE (UN	III: 8LQC57C6B	0)				
CARBOXYMETHYLC	ELLULOSE (UN	III: 05JZI7B19X)				
SO DIUM PHO SPHATE	, DIBASIC, ANH	HYDROUS (UNII: 22AI	DO 53M6 F)			
SACCHARIN SODIUM	(UNII: SB8ZUX4	40 TY)				
TITANIUM DIO XIDE (UNII: 15FIX9V2J	P)				
FD&C BLUE NO. 1 (UN	MI H3R47K3TBI	ור				
,		<i>)</i>)				
		-)				
Product Characte		blue	Score			
Product Characte Color			Score Size			
Product Characte Color Shape						
Product Characte Color Shape Flavor Contains		blue	Size			
Product Characte Color Shape Flavor		blue	Size			
Product Characte Color Shape Flavor Contains		blue	Size			
Product Characte Color Shape Flavor Contains Packaging	ristics	blue MINT	Size Imprint Code		art Date Marke	ting End Dat
Product Characte Color Shape Flavor Contains Packaging # Item Code	ristics	blue	Size Imprint Code	Marketing St	art Date Marke	ting End Dat
Product Characte Color Shape Flavor Contains Packaging I tem Code 1 NDC:63517-016-96	ristics J 144 in 1 CASE	blue MINT Package Descriptio	Size Imprint Code		art Date Marke	ting End Dat
Product Characte Color Shape Flavor Contains Packaging # Item Code 1 NDC:63517-016-96	ristics J 144 in 1 CASE	blue MINT	Size Imprint Code	Marketing St	art Date Marke	ting End Dat
Product Characte Color Shape Flavor Contains Packaging I tem Code NDC:63517-016-96	ristics I 144 in 1 CASE 24 g in 1 TUBE;	blue MINT Package Descriptio	Size Imprint Code	Marketing St	art Date Marke	ting End Dat
Product Characte Color Shape Flavor Contains Packaging I Item Code 1 NDC:63517-016-96 1 Marketing Info	ristics I 144 in 1 CASE 24 g in 1 TUBE; Drmation	blue MINT Package Descriptio	Size Imprint Code	Marketing St 09/09/2013		
Product Characte Color Shape Flavor Contains Packaging # Item Code	ristics I 144 in 1 CASE 24 g in 1 TUBE; Drmation	blue MINT Package Descriptio	Size Imprint Code	Marketing St		ting End Dat

Labeler - Cardinal Health (961027315)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

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