

HANDY SOLUTIONS CREST CAVITY PROTECTION FLUORIDE ANTICAVITY- sodium fluoride paste, dentifrice

Navajo Manufacturing 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.

Crest Cavity Protection Flouride Anticavity Toothpaste

Handy Solutions Crest Cavity Protection FLUORIDE ANTICAVITY TOOTHPASTE

Active ingredient

Sodium fluoride 0.243% (0.15% w/v fluoride ion)

Purpose

Anti-Cavity toothpaste

Use

helps protect against cavities

Warnings

Keep out of reach of children under 6 yrs. of age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 yrs. and older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist
- do not swallow
- to minimize swallowing use a pea-sized amount in children under 6
- supervise children's brushing until good habits are established
- children under 2 years : ask a dentist

Inactive ingredients

Sorbitol, water, hydrated silica, sodium lauryl sulfate, trisodium phosphate, flavor, sodium phosphate, cellulose gum, carbomer, sodium saccharin, titanium dioxide, blue 1

Questions or comments?

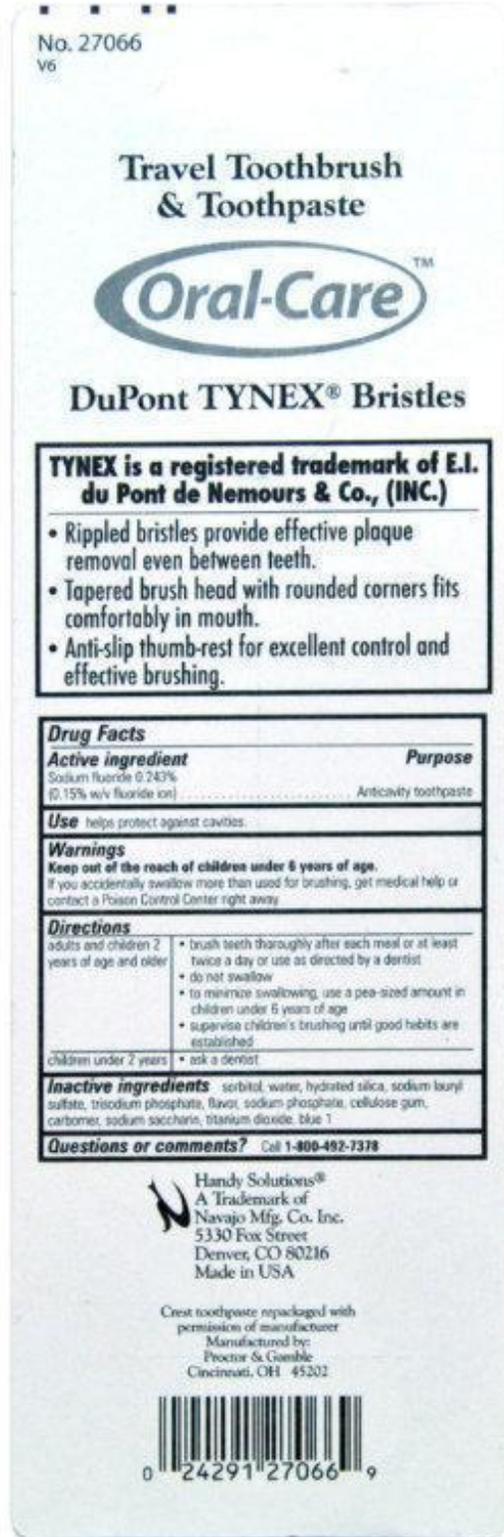
call toll-free **1-800-492-7378**

Handy Solutions Crest Cavity Protection FLUORIDE ANTICAVITY TOOTHPASTE

Handy Solutions Crest Cavity Protection FLUORIDE ANTICAVITY TOOTHPASTE 0.85oz/24g (67751-052-01)



Handy Solutions Crest Cavity Protection FLUORIDE ANTICAVITY TOOTHPASTE 0.85oz/24g (67751-052-02)



HANDY SOLUTIONS CREST CAVITY PROTECTION FLUORIDE ANTICAVITY
sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-052(NDC:37000-005)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-052-01	1 in 1 TUBE	08/21/2013	
1		24 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:67751-052-02	1 in 1 PACKAGE	08/21/2013	
2		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	06/24/2013	

Labeler - Navajo Manufacturing Company Inc (091917799)**Establishment**

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc		136941411	relabel(67751-052) , repack(67751-052)