

WESTERN FAMILY COMPLETE WHITENING - sodium fluoride paste, dentifrice
Western Family Foods, Inc

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Western Family Complete Whitening Fluoride Anticavity Toothpaste

Active Ingredient

Sodium Fluoride 0.243% (0.15% w/v fluoride ion)...Anticavity toothpaste

Helps protect against cavities.

As with all fluoride toothpastes, **keep out of reach of children under 6 years of age**. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

Adults and children 6 years and older Brush teeth thoroughly, preferably after each meal, or at least twice a day, or as directed by your dentist. Do not swallow.

Children between 6 and 12 years To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.

Children under 6 years Ask a dentist or physician.

Inactive Ingredients:

Sorbitol, Silica, Water, Glycerin, Sodium Lauryl Sulfate, Zinc Citrate, Titanium Dioxide, Cellulose Gum, Flavor, PVP, Sodium Benzoate, Tetrasodium Pyrophosphate, Sodium Saccharine, Sodium Hydroxide, Carageenan, Mica, FDC Blue No.1.

Principal Display Panel



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An Anticavity Fluoride Dentifrice

12181-9-11

Drug Facts		Drug Facts (continued)	
ACTIVE INGREDIENT Sodium Fluoride 0.243% (0.15% w/v fluoride ion)	PURPOSE Anticavity toothpaste	DIRECTIONS	
USE: Helps protect against cavities.		Adults and children 6 years and older	Brush teeth thoroughly, preferably after each meal, or at least twice a day, or as directed by your dentist. Do not swallow.
WARNINGS: As with all fluoride toothpastes, keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.		Children between 6 and 12 years	To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.
		Children under 6 years	Ask a dentist or physician.
INACTIVE INGREDIENTS: Sorbitol, Silica, Water, Glycerin, Sodium Lauryl Sulfate, Zinc Citrate, Titanium Dioxide, Cellulose Gum, Flavor, PVP, Sodium Benzoate, Tetrasodium Pyrophosphate, Sodium Saccharine, Sodium Hydroxide, Carageenan, Mica, FD&C Blue No. 1.			

WESTERN FAMILY COMPLETE WHITENING

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	2.43 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

ZINC CITRATE (UNII: K72I3DEX9B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
MICA (UNII: V8A1AW0880)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-003-01	18 1.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/24/2008	

Labeler - Western Family Foods, Inc (192166072)