

**WESTERN FAMILY WHITENING PLUS MINTY FRESH MOUTHWASH ANTICAVITY -  
sodium fluoride paste, dentifrice**

**Western Family Foods, 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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**Western Family Whitening Plus Minty Fresh Mouthwash Fluoride Anticavity Toothpaste**

**Active Ingredient**

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

**Directions**

**Adults and children  
2 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 under  
6 years of age**      To minimize swallowing, use a pea-sized  
amount and supervise brushing until  
good habits are established.

**Children under 2 years**      Ask a dentist or physician.

**Inactive Ingredients:**

Sorbitol, Water, Hydrated Silica, PEG-6, Sodium Lauryl Sulphate, Alcohol (1.14%), Flavor, Xanthan Gum, Carbomer, Sodium Benzoate, Titanium Dioxide, Tetrasodium Pyrophosphate, Sodium Saccharin, Triclosan, Blue 1, Yellow 4.

**Principal Display Panel**



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**An Anticavity Fluoride Dentifrice**

12182-4-IT

Drug Facts		Drug Facts (continued)	
<b>ACTIVE INGREDIENT</b>	<b>PURPOSE</b>	<b>DIRECTIONS</b>	
Sodium fluoride 0.243% (0.15% w/w fluoride ion) Anticavity toothpaste	Anticavity toothpaste	<b>Adults and children 2 years and older</b>	Brush teeth thoroughly, preferably after each meal, or at least twice a day, or as directed by your dentist. Do not swallow.
<b>USE:</b> Helps protect against cavities.		<b>Children under 6 years of age</b>	To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.
<b>WARNINGS:</b> 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.		<b>Children under 2 years</b>	Ask a dentist or physician.
<b>INACTIVE INGREDIENTS:</b> Sorbitol, Water, Hydrated Silica, PEG-6, Sodium Lauryl Sulphate, Alcohol (1.14%), Flavor, Xanthan Gum, Carbomer, Sodium Benzoate, Titanium Dioxide, Tetrasodium Pyrophosphate, Sodium Saccharin, Triclosan, Blue 1, Yellow 4.			

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.

**USE**

Helps protect against cavities.

**WESTERN FAMILY WHITENING PLUS MINTY FRESH MOUTHWASH ANTICAVITY**

sodium fluoride paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55312-182
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

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

## Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ALCOHOL (UNII: 3K9958V90M)	1.14 mg in 1 g
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRICLOSAN (UNII: 4NM5039Y5X)	

## Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT (Striped Mint)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-182-05	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)

Revised: 1/2011

Western Family Foods, Inc