

**WESTERN FAMILY TARTAR CONTROL - 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 Tartar Control Fluoride 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 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, Hydrated Silica, Water, PEG-6, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Titanium Dioxide, Sodium Phosphate, Tetrasodium Pyrophosphate, Sodium Saccharin, FDC Blue 1

**Principal Display Panel**



# Tartar Control

FLUORIDE TOOTHPASTE  
NET WT 8.2 OZ (232.4g)

Compare to Crest® Tartar Protection\*

Mint Paste

Proudly Distributed by  
Western Family Foods, Inc., P.O. Box 4057  
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### An Anticavity Fluoride Dentifrice

06267-B-TT

#### Drug Facts

**ACTIVE INGREDIENT**  
Sodium fluoride 0.243% (0.15% w/v fluoride ion)...Anticavity toothpaste

#### PURPOSE

Anticavity toothpaste

**USE:** Helps protect against cavities.

**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.

**INACTIVE INGREDIENTS:** Sorbitol, Hydrated Silica, Water, PEG-6, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Titanium Dioxide, Sodium Phosphate, Tetrasodium Pyrophosphate, Sodium Saccharin, FD&C Blue-1. Product of India.

#### Drug Facts (continued)

#### 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.

## WESTERN FAMILY TARTAR CONTROL

sodium fluoride paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-163
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 1g

### Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Mint Paste)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-163-07	232.4 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: 3/2011

Western Family Foods, Inc