

**WESTERN FAMILY CAVITY 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 Cavity 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, Sodium Saccharin

**Principal Display Panel**



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### An Anticavity Fluoride Dentifrice

06268-B-TT

Drug Facts		Drug Facts (continued)	
<b>ACTIVE INGREDIENT</b> Sodium fluoride 0.243% (0.15% w/v fluoride ion)	<b>PURPOSE</b> Anticavity toothpaste	<b>DIRECTIONS</b>	
<b>USE:</b> Helps protect against cavities.		<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>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 6 years of age</b>	To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.
		<b>Children under 2 years</b>	Ask a dentist or physician.
<b>INACTIVE INGREDIENTS:</b> Sorbitol, Hydrated Silica, Water, PEG-6, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Titanium Dioxide, Sodium Phosphate, Sodium Saccharin. Product of India.			

## WESTERN FAMILY CAVITY CONTROL

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55312-164
<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 1g

### Inactive Ingredients

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>POLYETHYLENE GLYCOL 300</b> (UNII: 5655G9Y8AQ)	
<b>SODIUM LAURYL SULFATE</b> (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>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-164-07	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