

WESTERN FAMILY SENSITIVE WHITENING FLUORIDE - potassium nitrate and sodium fluoride paste, dentifrice

Western Family Food, 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.

Western Family Sensitive Whitening Fluoride Toothpaste

Active Ingredient

Potassium Nitrate 5%.....Antihypersensitivity

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

USE

- builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact
- aids in the prevention of dental cavities

When using this product do not use longer than 4 weeks unless recommended by a dentist or doctor. **Stop and ask a dentist** if problem persists or worsens. Sensitive teeth may indicate a serious problem that may require prompt care by a dentist. **Keep out of reach of children.**

Directions

Adults and children 12 years and older Brush teeth for at least one minute, preferably after each meal, or at least twice a day, or as directed by your dentist. Be sure to brush sensitive areas.

Children under 12 years of age Consult a dentist or doctor.

Other information Store in a cool, dry place.

Inactive Ingredients

Sorbitol, Silica, Water, Sodium Lauryl Sulphate, Flavor, Cellulose gum, Titanium Dioxide, Sodium Benzoate, Sodium Phosphate, Tetrasodium Pyrophosphate, Sodium Saccharin

Principal Display Panel



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An Anticavity Fluoride Dentifrice

04629-A-TT

Drug Facts		Drug Facts (continued)	
ACTIVE INGREDIENT Potassium nitrate 5% Sodium fluoride 0.243% (0.15% w/v fluoride ion)...	PURPOSE Antihypersensitivity Anticavity Toothpaste	If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.	
USES: • builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact • aids in the prevention of dental cavities	WARNINGS: When using this product do not use longer than 4 weeks unless recommended by a dentist or doctor. Stop and ask a dentist if problem persists or worsens. Sensitive teeth may indicate a serious problem that may require prompt care by a dentist. Keep out of reach of children. ▶	DIRECTIONS	
		Adults and children 12 years and older	Brush teeth for at least one minute, preferably after each meal, or at least twice a day, or as directed by your dentist. Be sure to brush sensitive areas.
		Children under 12 years of age	Consult a dentist or doctor.
		Other information	Store in a cool, dry place.
INACTIVE INGREDIENTS: Sorbitol, Silica, Water, Sodium Lauryl Sulphate, Flavor, Cellulose Gum, Titanium Dioxide, Sodium Benzoate, Sodium Phosphate, Tetrasodium Pyrophosphate, Sodium Saccharin. Product of India.			

WESTERN FAMILY SENSITIVE WHITENING FLUORIDE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-158
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM NITRATE	5 mg in 1 g
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)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-158-09	113 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/02/2007	

Labeler - Western Family Food, Inc. (192166072)