

FAMILY WELLNESS SENSITIVE EXTRA WHITENING- potassium nitrate and sodium fluoride paste

Family Wellness

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.

Family Wellness Sensitive Extra Whitening

Active Ingredients

Potassium nitrate 5%..... Antihypersensitivity

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

USES

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

Purpose

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

Stop use and ask a dentist if

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- pain/sensitivity still persists after 4 weeks of use.

Keep out of reach of children

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

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 of the teeth.

Children under 12 years of age Consult a dentist or doctor

Other information Store in a cool, dry place.

Inactive ingredients

sorbitol, water, silica, sodium lauryl sulfate, flavor, cellulose gum, titanium dioxide, sodium benzoate, sodium phosphate, tetrasodium pyrophosphate, sodium saccharin.



FAMILY WELLNESS SENSITIVE EXTRA WHITENING

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-900
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM PHOSPHATE (UNII: SE337SVY37)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
Product Characteristics				
Color	white (Sensitive)	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-900-01	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	04/11/2013		

Labeler - Family Wellness (024472631)