

IBRITE- sodium fluoride, potassium nitrate paste, dentifrice
Pac-Dent International 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.

Drug Facts

Active ingredient

Purpose

Sodium fluoride 0.254%.....Anticavity toothpaste
Potassium nitrate 3%.....Antisensitivity

Inactive ingredients

Glycerin, hydrated silica, PEG-8, water, sodium lauryl sulfate, sodium citrate, trisodium polyphosphate, sodium pyrophosphate, flavors, carboxymethyl cellulose sodium, sodium saccharin, FD&C blue #1, green #3.

Warnings Stop use and ask a dentist if sensitivity persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center.

Directions

- Adults and children 12 years of age and older: Apply at least a 1-inch strip of the toothpaste onto a soft bristle toothbrush.
- Brush teeth thoroughly for at least one minute, preferably after each meal or at least twice a day (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth.

Directions (continued)

- Children under 12 years of age: Consult a dentist or physician.
- Other Information: Store below 86°F (30°C).

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Directions (continued)

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

Warnings Stop use and ask a dentist if sensitivity persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center.

Whitening • Sensitivity Relief | Fights Tartar | Helps prevent Cavities • Gingivitis • Plaque



IBRITE

sodium fluoride, potassium nitrate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68983-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.54 mg in 1 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68983-006-02	1 in 1 CARTON	02/01/2016	
1	NDC:68983-006-01	140 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68983-006-04	1 in 1 CARTON	02/01/2016	
2	NDC:68983-006-03	25 g in 1 TUBE; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/01/2016	

Labeler - Pac-Dent International Inc. (073253994)

Registrant - Pac-Dent International Inc. (073253994)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 12/2015

Pac-Dent International Inc.