SENSITIVE TEETH- potassium nitrate paste
The Green Beaver Company Ltd.

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.

Active ingredients

Postassium nitrate, 5%

Purpose

Antisensitivity

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

Use builds increasing protection against painful sensitivity of the teeth to cold, acids, sweets, or contact

Warnings

When using this product, if pain/sensitivity still persists after 4 weeks or use, please visit your dentist

Directions

- adults and children 12 years of age and older
- Apply at least a 1-inch strip of the product onto soft bristle toothbrush
- Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist
- Make sure to brush all sensitive areas of the teeth
- Children under 12 years of age: consult a dentist or doctor

Inactive ingredients

Calcium carbonate, Sorbitol, Agua, Glycerin, Hydrate Silica, Xynthol, Coco-glucoside, Xanthan Gum, Mentha Viridis (Spearmint) Leaf Oil, Menthol, Leuconostoc/Radish Root Ferment Filtrate

SENSITIVE TEETH

potassium nitrate paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76098-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
COCO GLUCOSIDE (UNII: ICS790225B)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SORBITOL (UNII: 506T60A25R)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MENTHA SPICATA (UNII: O2H83I4PUN)	
MENTHOL (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76098-001-01	75 mL in 1 BOX; Type 0: Not a Combination Product	07/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/06/2017	

Labeler - The Green Beaver Company Ltd. (243807018)

Establishment

Name	Address	ID/FEI	Business Operations
Dermolab Pharma Ltee		245414743	manufacture(76098-001)

Revised: 8/2017 The Green Beaver Company Ltd.