EARLY BIRD WINTERGREEN AND PEPPERMINT- potassium nitrate, sodium fluoride paste
Smiletwice, 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.

Early Bird Wintergreen and Peppermint Toothpaste

Drug Facts

Active ingredients

Potassium Nitrate 5%
Sodium Fluoride 0.240% (0.15% w/v Fluoride ion)

Purpose

Antihypersensitivity

Anticavity

Uses

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

Warnings

When using this product,

if pain/sensitivity still persists after 4 weeks of use, please visit your dentist.

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.

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

Inactive Ingredients

Water, Hydrated Silica, Sorbitol, Glycerin, Pentasodium Triphosphate, Cocamidopropyl Betaine, Flavor, Sodium Acorbyl Phosphate (Vitamin C), Retinyl Palmitate (Vitamin A), Tocopherol (Vitamin E),

Aloe Barbadensis Leaf Juice (Aloe Vera), Xylitol, Sodium Saccharin, Sucralose, Lauryl Glucoside, Cellulose Gum, Titanium Dioxide, Sodium Benzoate, Citric Acid.

Package Labeling:

twice™

EARLY BIRD™

Wintergreen & Peppermint

PREMIUM TOOTHPASTE

teeth whitening
cavity prevention
sensitivity relief

3.4 oz · 96 grams

TOOTHPASTE SO NICE, YOU'LL SMILE TWICE™

EARLY BIRD is your anytime wakeup call.
The freshest clean you've ever seen.

Infused with antioxidants and vitamins.
NO SLS · NO triclosan · NO PEGs · NO parabens

Better smiles start with better toothpaste.™

GF V GMO

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Purchase, NY 10577
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EARLY BIRD WINTERGREEN AND PEPPERMINT

potassium nitrate, sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72164-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.4 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
XYLITOL (UNII: VCQ006KQ1E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72164-001-01	96 g in 1 TUBE; Type 0: Not a Combination Product	05/18/2018	
2	NDC:72164-001-00	2 in 1 BOX	05/18/2018	12/31/2019
2		96 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	05/18/2018	

Labeler - Smiletwice, Inc. (117404286)

Revised: 2/2020 Smiletwice, Inc.