

4 PACK- potassium nitrate, sodium fluoride
Twice Smiles LLC

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.

4 Pack

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 Ascorbyl 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.

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Twilight Peppermint with Vanilla and Lavender Toothpaste, 96g (72164-000-00)

twice™

TWILIGHT™
Peppermint with Vanilla & Lavender

PREMIUM TOOTHPASTE

teeth whitening
cavity prevention
sensitivity relief

3.4 oz · 96 grams

TOOTHPASTE SO NICE, YOU'LL SMILE TWICE™

TWILIGHT is your smooth transition from morning to night. Relax and refresh with spa-like ease.

Infused with antioxidants and vitamins.

NO SLS · NO triclosan · NO PEGs · NO parabens

Better smiles start with better toothpaste.™



Drug Facts

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Distributed by Twice Smiles LLC
Purchase, NY 10577
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Your purchase helps make an impact.
Visit smiletwice.com to learn more.



Early Bird Wintergreen and Peppermint Toothpaste 96g (72164-001-00)

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.™



Drug Facts

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Distributed by Twice Smiles LLC
Purchase, NY 10577

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Your purchase helps make an impact.

Visit smiletwice.com to learn more.



4 PACK

potassium nitrate, sodium fluoride kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72164-101

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72164-101-04	1 in 1 KIT	09/14/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 TUBE	192 g
Part 2	2 TUBE	192 g

Part 1 of 2

TWILIGHT PEPPERMINT WITH VANILLA AND LAVENDER

potassium nitrate, sodium fluoride paste

Product Information

Item Code (Source)	NDC:72164-000
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:72164-000-00	2 in 1 BOX		
1		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	09/14/2018	

Part 2 of 2

EARLY BIRD WINTERGREEN AND PEPPERMINT

potassium nitrate, sodium fluoride paste

Product Information

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)	
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OTC monograph not final	part356	09/14/2018	

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OTC monograph not final	part356	09/14/2018	

Labeler - Twice Smiles LLC (081061747)