

**MINI DUO- potassium nitrate, sodium fluoride  
Smiletwice, Inc.**

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**Mini Toothpaste-Duo KIT**

***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.

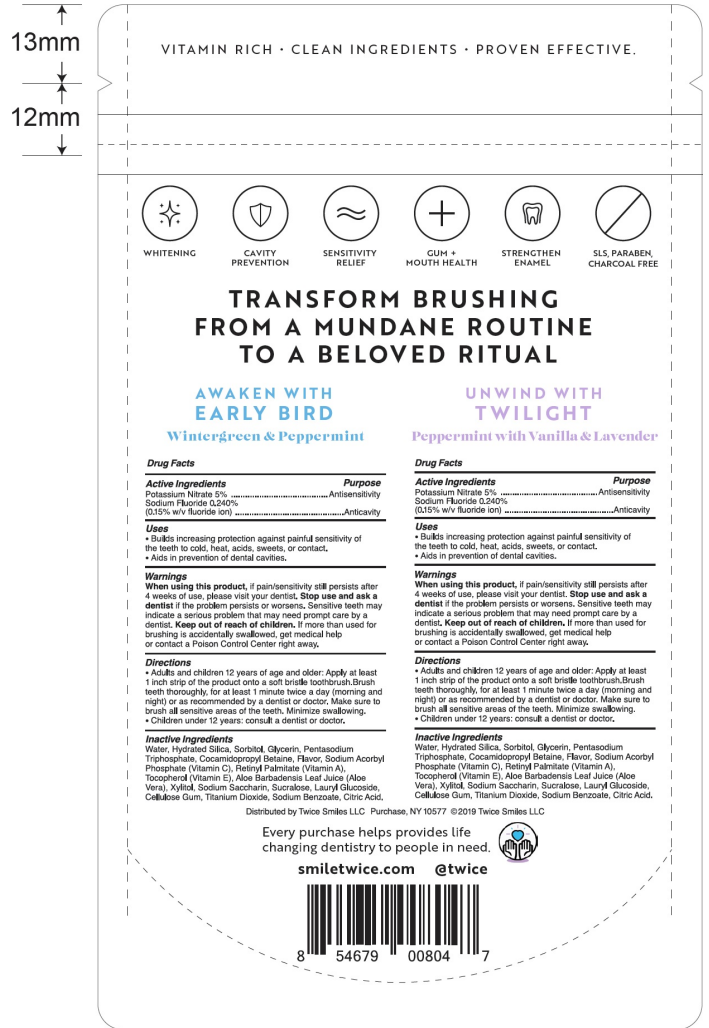
***Directions***

- 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: KIT 72164-102-23**



**Package Labeling: 72164-001-01**

twice®

EARLY BIRD  
Wintergreen & Peppermint

PREMIUM  
TOOTHPASTE

0.8 oz · 23 grams

WAKE-UP

Your mouth's minty wake-up call,  
whenever it needs to hit refresh.

NO SLS · NO triclosan · NO parabens

Visit us at [smiletwice.com](http://smiletwice.com)  
to re-order and unlock your  
healthiest & brightest smile.



**Active Ingredients**

Potassium Nitrate 5%	.....Antisensitivity
Sodium Fluoride 0.240%	.....Anticavity


**Purpose**

**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.

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Purchase, NY 10577  
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Package Labeling: 72164-000-02

 <p><b>twice</b><sup>®</sup></p> <p><b>PREMIUM TOOTHPASTE</b></p> <p>0.8 oz · 23 grams</p>	<p><b>TWILIGHT</b></p> <p><b>Peppermint with Vanilla &amp; Lavender</b></p>	<p><b>WIND-DOWN</b></p> <p>Like a spa moment for your smile, Twilight puts the "oo" in smooth.</p> <p>NO SLS · NO triclosan · NO parabens</p> <p>Visit us at <a href="http://smiletwice.com">smiletwice.com</a> to re-order and unlock your healthiest &amp; brightest smile.</p>   <p><b>Active Ingredients</b></p> <p>Potassium Nitrate 5% .....Antisensitivity Sodium Fluoride 0.240% .....Anticavity</p> <p><b>Warnings</b></p> <p>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.</p> <p>Distributed by Twice Smiles LLC Purchase, NY 10577 © 2019 Twice Smiles LLC</p>	

<b>MINI DUO</b>				
potassium nitrate, sodium fluoride kit				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72164-102	
<b>Packaging</b>				
#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>

1	NDC:72164-102-23	1 in 1 KIT	03/01/2020
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### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	23 g
Part 2	1 TUBE	23 g

### Part 1 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:Q80VPU4080)	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)	
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:72164-001-02	23 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 Drug	M022	03/01/2020	

## Part 2 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:Q80VPU4080)	FLUORIDE ION	2.4 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
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)	
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:72164-000-02	23 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 Drug	M022	03/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	part355B	03/01/2020	

**Labeler** - Smiletwice, Inc. (117404286)

Revised: 12/2023

Smiletwice, Inc.