# BRUSH BUDDIES SENSITIVE EXTRA WHITENING- potassium nitrate, sodium fluoride paste, dentifrice Ashtel Studios, 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.

-----

## BB SENSITIVE TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

#### **Drug Facts**

#### Active ingredients

Potassium Nitrate 5% Sodium Fluoride 0.24% (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 the prevention of dental cavities.

#### Warnings

**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. • pain/sensitivity still persists after 4 weeks of use.

#### Keep out of reach of children under 12 years of age.

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 & older: apply at least a 1-inch strip of the product onto a soft bristle toothbrush
- brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. Make sure to brush all sensitive areas of the teeth.
- minimize swallowing. Spit out after brushing.
- children under 12 years of age: Consult a dentist or doctor.

#### Inactive ingredients

Sorbitol, Hydrated Silica, Treated Water, PEG-1500, Sodium Lauryl Sulphate, Flavor, Glycerin, Cellulose Gum, Tetrasodium Pyrophosphate, Titanium Dioxide, Sodium Benzoate, Trisodium Phosphate, Sodium Saccharin, Sodium Hydroxide, Methylparaben, Propylparaben

#### Questions or comments?

call toll free 1-877-274-8358

# TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION FRESH MINT

- FRESHENS BREATH
- STRENGTHENS TEETH WITH ACTIVE FLUORIDE

#### Compares to the active ingredients in Sensodyne® Extra Whitening\*

\*This product is not manufactured or distributed by GSK Consumer Healthcare, owner of the registered trademark Sensodyne<sup>®</sup>.

DESIGNED IN U.S.A. • MADE IN INDIA

Brush Buddies® WWW.BRUSHBUDDIES.COM

QUESTIONS OR COMMENTS? 1-877-274-8358 TOLL FREE IN USA 1-909-434-0911 INTERNATIONAL

PATENTS, COPYRIGHTS & TRADEMARKS GRANTED OR PENDING WORLDWIDE DISTRIBUTED BY ASHTEL STUDIOS INC. ONTARIO, CALIFORNIA 91761

#### **Packaging**

#### **INNER PACKAGE LABEL**

COMMENTS? / QUESTIONS? / COMMENTAIRES? 1-877-274-8358 TOLL FREE IN U.S.A. • 1-909-434-0911 INTERNATIONAL





\*This product is not manufactured or distributed by GSK Consumer Healthcare, owner of the registered trademark Sensodyne?

Purpose

# tem # 32744

#### Drug Facts

#### Active ingredients

Potassium Nitrate 5%......Antihypersensitivity Sodium Fluoride 0.24% (0.15 % w/v Fluoride ion)..Anticavity

Uses • builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact • aids in the prevention of dental cavities.

Warnings 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.

• pain/sensitivity still persists after 4 weeks of use.

Keep out of reach of children under 12 years of age.
If more than used for brushing is accidentally swallowed, get
medical help or contact a Poison Control Center right away.

#### Drug Facts (continued)

#### Directions

- adults and children 12 years & older: apply at least a 1-inch strip of the product onto a soft bristle toothbrush brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. Make sure to brush all sensitive areas of the teeth
- minimize swallowing. Spit out after brushing.
   children under 12 years of age: Consult a dentist or doctor.

#### Inactive ingredients

Sorbitol, Hydrated Silica, Treated Water, PEG -1500, Sodium Lauryl Sulphate, Flavor, Glycerin, Cellulose Gum, Tetrasodium Pyrophosphate, Titanium Dioxide, Sodium Benzoate, Trisodium Phosphate, Sodium Saccharin, Sodium Hydroxide, Methylparaben, Propylparaben

Questions or comments? Call toll free 1-877-274-8358

DISTRIBUTED BY ASHTEL STUDIOS INC., • ONTARIO, CALIFORNIA 91761 PATENTS, COPYRIGHTS & TRADEMARKS GRANTED OR PENDING WORLDWIDE

C. No. DNH/COS/DNH/52 1222103301

DESIGNED IN USA • MADE IN INDIA

#### **OUTER PACKAGE LABEL**



NET WT 4.0 OZ (113g)



#### Drug Facts

**FRESH MINT** 

rate 5%......Antihyperse de 0.24% (0.15 % w/v Fluoride ion)..An

Keep out of reach of children under 12 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

children 12 years & older: - apply at least a of the product onto a soft bristle toothbrush thoroughly after meals or at least twice a day or ted by a dentist. Make sure to brush at sensitive teeth.

ts? Call toll free 1-877-274-8358

C. No. DNH/COS/DNH/52

This product is not manufactured or distributed by GSK Consumer Healthcare, owner of the registered trademark Sensodyne. DESIGNED IN U.S.A. · MADE IN INDIA

#### BrushBuddies\*

QUESTIONS OR COMMENTS?
1-977-274-8358 TOLL FREE IN USA
1-909-434-9911 INTERNATIONAL
PATENTS, COPYRIGHTS & TRADEMARKS
GRANTED OR PENDING WORLDWIDE DISTRIBUTED BY ASHTEL STUD



potassium nitrate, sodium fluoride paste, dentifrice

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70108-079

Route of Administration DENTAL

### Active Ingredient/Active Moiety

Ingredient Name

POTASSIUM NITRATE (UNII: RU45X2JNOZ) (NITRATE ION - UNII:T93E9Y2844)

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)

SODIUM FLUORIDE

SODIUM FLUORIDE

O.24 g in 100 g

#### **Inactive Ingredients**

1	ingredient Name	Strength
ı	SORBITOL (UNII: 506T60A25R)	
ı	HYDRATED SILICA (UNII: Y6O7T4G8P9)	

WATER (UNII: 059QF0KO0R)

POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)

**SODIUM LAURYL SULFATE** (UNII: 368GB5141J)

**GLYCERIN** (UNII: PDC6A3C0OX)

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)

**SODIUM PYROPHOSPHATE** (UNII: O352864B8Z)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

SODIUM BENZOATE (UNII: 0J245FE5EU)

SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZ O3QZ)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

METHYLPARABEN (UNII: A2I8C7HI9T)

PROPYLPARABEN (UNII: Z8IX2SC10H)

#### **Product Characteristics**

Color		Score
Shape		Size
Flavor	MINT (Fresh mint)	Imprint Code
Contains		

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70108-079- 01	1 in 1 BOX	09/07/2023	
1		113 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 final	M022	09/07/2023				

### Labeler - Ashtel Studios, Inc. (148689180)

Revised: 9/2023 Ashtel Studios, Inc.