

ULTIMATE WHITE SENSITIVE 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.

ULTIMATE *white*TM SENSITIVE TOOTHPASTE

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 amount used for brushing is accidentally swallowed, seek medical help or contact a Poison Control Center immediately.

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 for at least one minute, preferably after each meal or at least twice a day (morning and evening) as recommended by a dentist or physician. 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.

Other information

Store at room temperature 68-77°F (20-25°C)

Inactive ingredients

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

Questions or comments?

1-877-274-8358

TWIN PACK

SENSITIVE TOOTHPASTE

MAXIMUM STRENGTH WITH FLUORIDE

**FOR SENSITIVE TEETH AND CAVITY PROTECTION
RELIEVES PAINFUL SENSITIVITY**

EXTRA WHITENING

**DESIGNED IN U.S.A.
MANUFACTURED IN INDIA**

**Brush Buddies®
BRUSHBUDDIES.COM ONTARIO, CA 91761**

**QUESTIONS OR COMMENTS?
1-877-274-8358 TOLL FREE IN U.S.A.
1-909-434-0911 INTERNATIONAL**

**COPYRIGHTS AND TRADEMARKS GRANTED OR PENDING WORLDWIDE
DISTRIBUTED BY ASHTEL STUDIOS INC.**

Packaging

INNER TUBE LABEL



whiteTM

MAXIMUM STRENGTH WITH FLUORIDE
FOR SENSITIVE TEETH AND CAVITY PROTECTION
RELIEVES PAINFUL SENSITIVITY

NET WT 3.5 OZ (99g)

Brush Buddies[®]
 WWW.BRUSHBUDDIES.COM



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

PATENTS, COPYRIGHTS AND TRADEMARKS
GRANTED OR PENDING WORLDWIDE

DISTRIBUTED BY ASHTEL STUDIOS INC., ONTARIO, CA 91761 ITEM #: 39630 • C. No. DNH/COS/DNH/52 • 1222103111
 DESIGNED IN U.S.A • MANUFACTURED IN INDIA

<p>Drug Facts</p>	<p>Drug Facts (continued)</p>
<p>Active ingredients</p> <p>Potassium Nitrate (5%)..... Antihypersensitivity Sodium Fluoride 0.24% (0.15% w/v fluoride ion)..... Anticavity</p>	<p>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 for at least one minute, preferably after each meal or at least twice a day (morning and evening) as recommended by a dentist or physician. 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.</p>
<p>Uses Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact • aids in the prevention of dental cavities</p>	<p>Other information Store at room temperature 68-77°F (20-25°C)</p>
<p>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 amount used for brushing is accidentally swallowed, seek medical help or contact a Poison Control Center immediately. ▶</p>	<p>Inactive ingredients Sorbitol, Hydrated Silica, Treated Water, PEG-1500, Sodium Lauryl Sulfate, Flavor, Glycerin, Cellulose Gum, Tetrasodium Pyrophosphate, Titanium Dioxide, Sodium Benzoate, Trisodium Phosphate, Sodium Saccharin, Sodium Hydroxide, Methylparaben, Propylparaben</p>

OUTER BOX LABEL

ULTIMATE whiteTM

TWIN PACK

SENSITIVE TOOTHPASTE

MAXIMUM STRENGTH WITH FLUORIDE
FOR SENSITIVE TEETH AND CAVITY PROTECTION
RELIEVES PAINFUL SENSITIVITY

EXTRA WHITENING

TWO 3.5 OZ (99g) TUBES • TOTAL NET WT 7 OZ (198g)

Drug Facts

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

Purpose Antihypersensitivity

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 for at least one minute, preferably after each meal or at least twice a day (morning and evening) as recommended by a dentist or physician. 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.

Other information Store at room temperature 68-77°F (20-25°C)

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

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 amount used for brushing is accidentally swallowed, seek medical help or contact a Poison Control Center immediately.

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

Questions or comments? 1-877-274-8358



ULTIMATE WHITE SENSITIVE WHITENING

potassium nitrate, sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70108-075
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7533A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70108-075-01	2 in 1 BOX	03/24/2023	
1		99 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	03/24/2023	

Labeler - Ashtel Studios, Inc. (148689180)

Revised: 3/2023

Ashtel Studios, Inc.