### SENSODYNE- potassium nitrate and sodium fluoride paste Haleon US Holdings LLC

-----

# **Drug Facts**

#### Active ingredients

Potassium nitrate 5%

Sodium fluoride 0.24% (0.15% w/v fluoride ion)

#### Purposes

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.

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 a 1-inch strip of the product onto a soft bristle toothbrush.
  - brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. 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

• do not store above 30°C (86°F)

# Inactive ingredients

water, hydrated silica, sorbitol, glycerin, pentasodium triphosphate, PEG-8, flavor, titanium dioxide, sodium methyl cocoyl taurate, cocamidopropyl betaine, xanthan gum, sodium hydroxide, sodium saccharin, sucralose

### **Questions or comments?**

1-866-844-2797

# Additional Information (Full Protection)

# ALWAYS FOLLOW THE LABEL

#### What are sensitive teeth?

Lots of people hove sensitive teeth. When enamel is worn away (through eating everyday acidic food or drinks) or gums recede, the dentin underneath becomes exposed. This can lead to tooth sensitivity, for example, with cold and hot food and drinks.

# What does Sensodyne do?

Sensodyne provides daily care for sensitive teeth\* plus all the benefits you would expect from a daily

fluoride toothpaste - strong teeth and freshness.

\*with twice daily brushing.

**Exposed Dentin** 

# 24/7 Sensitivity Protection\*

+ Strong & Healthy Teeth

# **Use Sensodyne Full Protection**

#### + Whitening twice daily:

- Long lasting sensitivity protection\* every day
- Contains fluoride to protect against cavities

Trademarks are owned by or licensed to the GSK group of companies.

© 2020 GSK group of companies or its licensor.

Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

# Additional Information (Tartar Control)

# **Use Sensodyne Tartar Control**

# + Whitening twice daily:

- Long lasting sensitivity protection\* every day
- Contains fluoride to protect against cavities

# **Principal Display Panel**

# **#1 DENTIST RECOMMENDED BRAND HALEON**

# SENSODYNE

# TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 SENSITIVITY PROTECTION\* + Strong & Healthy Teeth

# Full Protection + Whitening

with triple action cleaning formula

NET WT 4.0 OZ (113 g)

6200000208034



# Principal Display Panel NDC 0135-0551-04 #1 DENTIST RECOMMENDED BRAND SENSODYNE TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION 24/7 SENSITIVITY PROTECTION\* + Strong & Healthy Teeth Tartar Control + Whitening NET WT 4.0 OZ (113 g)

6200000053367

SE



# SENSODYNE

potassium nitrate and sodium fluoride paste

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC		NDC:02	C:0135-0550	
Route of Administration	DENTAL					
Active Ingredient/Active	Moiety					
Ingre	dient Name		<b>Basis of Stre</b>	ength	Strength	
POTASSIUM NITRATE (UNII: RU45	X2JN0Z) (NITRATE ION - UNI	I:T93E9Y2844)	POTASSIUM NITE	RATE	50 mg in 1 g	
SODIUM FLUORIDE (UNII: 8ZYQ14	174W7) (FLUORIDE ION - UN	ll:Q80VPU408O)	FLUORIDE ION		1.1 mg in 1 g	
Inactive Ingredients					~	
	In a second second blacks a				··	
	Ingredient Name				Strength	
WATER (UNII: 059QF0KO0R)					Strength	
HYDRATED SILICA (UNII: Y607T40					Strength	
HYDRATED SILICA (UNII: Y6O7T4G SORBITOL (UNII: 506T60A25R)					Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C00X)	58P9)	2257)			Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C00X) SODIUM TRIPOLYPHOSPHATE AI	88P9) NHYDROUS (UNII: 9SW4PFE	D2FZ)			Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C00X) SODIUM TRIPOLYPHOSPHATE AI POLYETHYLENE GLYCOL 400 (UR	58P9) NHYDROUS (UNII: 95W4PFE NII: B6978945GQ)	D2FZ)			Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C0OX) SODIUM TRIPOLYPHOSPHATE AI POLYETHYLENE GLYCOL 400 (UNII) TITANIUM DIOXIDE (UNII: 15FIX9V	58P9) NHYDROUS (UNII: 9SW4PFE NII: B697894SGQ) 2JP)	D2FZ)			Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C00X) SODIUM TRIPOLYPHOSPHATE AI POLYETHYLENE GLYCOL 400 (UNI TITANIUM DIOXIDE (UNII: 15FIX9V COCAMIDOPROPYL BETAINE (UN	58P9) NHYDROUS (UNII: 95W4PFE NII: B697894SGQ) 2JP) III: 50CF3O11KX)	D2FZ)			Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C0OX) SODIUM TRIPOLYPHOSPHATE AI POLYETHYLENE GLYCOL 400 (UNI TITANIUM DIOXIDE (UNII: 15FIX9V	58P9) NHYDROUS (UNII: 9SW4PFE NII: B697894SGQ) 2JP) III: 50CF3011KX) ATE (UNII: JVL98CG53G)	D2FZ)			Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C00X) SODIUM TRIPOLYPHOSPHATE AI POLYETHYLENE GLYCOL 400 (UN TITANIUM DIOXIDE (UNII: 15FIX9V COCAMIDOPROPYL BETAINE (UN SODIUM METHYL COCOYL TAUR XANTHAN GUM (UNII: TTV12P4NEE	58P9) NHYDROUS (UNII: 9SW4PFE NII: B697894SGQ) 2JP) III: 5OCF3O11KX) ATE (UNII: JVL98CG53G)	D2FZ)			Strength	
HYDRATED SILICA (UNII: Y607T4G SORBITOL (UNII: 506T60A25R) GLYCERIN (UNII: PDC6A3C0OX) SODIUM TRIPOLYPHOSPHATE AI POLYETHYLENE GLYCOL 400 (UN TITANIUM DIOXIDE (UNII: 15FIX9V COCAMIDOPROPYL BETAINE (UN SODIUM METHYL COCOYL TAUR	58P9) NHYDROUS (UNII: 9SW4PFE NII: B697894SGQ) 2JP) III: 5OCF3O11KX) III: 5OCF3O11KX) IATE (UNII: JVL98CG53G) III:	D2FZ)			Strength	

#### Product Characteristics white Color Score Shape Size Flavor MINT **Imprint Code** Contains

211	ackaging			Mark	eting Start	Marl	ceting End
ŧ	Item Code	Pao	ckage Description	Mark	Date	Mar	Date
L	NDC:0135-0550- 04	1 in 1 CARTON	I	02/17/20	04		
L		113 g in 1 TUE Product	BE; Type 0: Not a Combination				
Л	arketing	Informat	ion				
•	Marketing		tion Number or Monogra	iph Ma	rketing Start	Mar	rketing End
	Category		Citation		Date		Date
т	C Monograph Dru	ug M022		02/17	/2004		
		_					
	INSODYNE	_					
0	tassium nitrate	e and sodium	n fluoride paste				
P	roduct Infor	mation					
Pr	oduct Type		HUMAN OTC DRUG	em Code (	Source)	NDC:0	135-0551
	oute of Admini	stration	DENTAL				
Ad	tive Inaredi	ent/Active	Moiety				
Ac	ctive Ingredi				Basis of Str	ength	Strengtl
	-	Ingre	dient Name	93E9Y2844)	Basis of Str	-	-
PO	TASSIUM NITRA	Ingre ATE (UNII: RU45				-	50 mg in 1
PO	TASSIUM NITRA	Ingre ATE (UNII: RU45	dient Name X2JN0Z) (NITRATE ION - UNII:T		POTASSIUM NIT	-	50 mg in 1
P0 50	DTASSIUM NITRA	ingre Ate (Unii: RU45 E (Unii: 8ZYQ14	dient Name X2JN0Z) (NITRATE ION - UNII:T		POTASSIUM NIT	-	50 mg in 1
P0 50	TASSIUM NITRA	ingre Ate (Unii: RU45 E (Unii: 8ZYQ14	edient Name X2JN0Z) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C		POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
P0 50	active Ingre	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients	dient Name X2JN0Z) (NITRATE ION - UNII:T		POTASSIUM NIT	-	Strength 50 mg in 1 1.1 mg in 1 Strength
P0 50 In	ATER (UNII: 059Q	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients	edient Name X2JN0Z) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C Ingredient Name		POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
PO SO In W/	active Ingre	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients FOKOOR) (UNII: Y6O7T4G	edient Name X2JN0Z) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C Ingredient Name		POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
PO SO In W/ HY	ATER (UNII: 059Q TRATED SILICA	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 edients FOKOOR) (UNII: Y6O7T46 D6T60A25R)	edient Name X2JN0Z) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C Ingredient Name		POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
PO SO In W/ HY SO GL	active Ingre ATER (UNII: 059Q DRATED SILICA RBITOL (UNII: 50 YCERIN (UNII: PE	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients FOKOOR) (UNII: Y607T40 D6T60A25R) DC6A3C0OX)	edient Name X2JNOZ) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C Ingredient Name	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
>0 50 1 n -1 Y 50 50	ATER (UNII: 059Q DRATED SILICA PRBITOL (UNII: 50 YCERIN (UNII: PE	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 edients FOKOOR) (UNII: Y6O7T4G D6T60A25R) D66A3C0OX) PHOSPHATE AI	Adient Name X2JNOZ) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C Ingredient Name 68P9)	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
	ATER (UNII: 059Q DRATED SILICA RBITOL (UNII: 50 YCERIN (UNII: 9D DIUM TRIPOLYF	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 edients FOKOOR) (UNII: Y6O7T4G D6T60A25R) DC6A3C0OX) PHOSPHATE AI LYCOL 400 (UI	edient Name X2JNOZ) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C Ingredient Name 58P9) NHYDROUS (UNII: 9SW4PFD2F NII: B697894SGQ)	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
	ATER (UNII: 059Q DIUM FLUORIDI ATER (UNII: 059Q DRATED SILICA RBITOL (UNII: 50 YCERIN (UNII: 50 YCERIN (UNII: 9D DIUM TRIPOLYF DIUM TRIPOLYF DIYETHYLENE GI	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients FOKOOR) (UNII: Y6O7T46 D6T60A25R) DC6A3C0OX) PHOSPHATE AI LYCOL 400 (UI E (UNII: 15FIX9V	Adient Name X2JNOZ) (NITRATE ION - UNII:T 474W7) (FLUORIDE ION - UNII:C Ingredient Name 58P9) NHYDROUS (UNII: 95W4PFD2F NII: B697894SGQ) 72JP)	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
	ATER (UNII: 059Q DRATED SILICA ORBITOL (UNII: 50 YCERIN (	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 edients FOKOOR) (UNII: Y6O7T4G D6T60A25R) DC6A3C0OX) PHOSPHATE AI LYCOL 400 (UI E (UNII: 15FIX9V L BETAINE (UN	edient Name   X2JN0Z ) (NITRATE ION - UNII:T   \$74W7) (FLUORIDE ION - UNII:C   Ingredient Name   \$8P9)   NHYDROUS (UNII: 9SW4PFD2F   NII: B697894SGQ)   [2JP)   III: 50CF3011KX)	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
	ATER (UNII: 059Q DRATED SILICA ORBITOL (UNII: 50 YCERIN (	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients FOKOOR) (UNII: Y6O7T4G D6T60A25R) DC6A3C0OX) PHOSPHATE AI LYCOL 400 (UI E (UNII: 15FIX9V L BETAINE (UN COCOYL TAUR	edient Name   X2JN0Z) (NITRATE ION - UNII:T   \$74W7) (FLUORIDE ION - UNII:C   Ingredient Name   \$8P9)   NHYDROUS (UNII: 9SW4PFD2F   NII: B697894SGQ)   '2JP)   III: 50CF3011KX)   *ATE (UNII: JVL98CG53G)	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
	ATER (UNII: 059Q ATER (UNII: 059Q DRATED SILICA RBITOL (UNII: 50 YCERIN (UNII: 50 YCERIN (UNII: 92 DIUM TRIPOLYF OLYETHYLENE G TANIUM DIOXIDE CAMIDOPROPY	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 edients FOKOOR) (UNII: Y6O7T4G D6T60A25R) DC6A3C0OX) PHOSPHATE AI LYCOL 400 (UI E (UNII: 15FIX9V L BETAINE (UN COCOYL TAUR NII: TTV12P4NEE	edient Name   X2JN0Z) (NITRATE ION - UNII:T   \$74W7) (FLUORIDE ION - UNII:C   Ingredient Name   \$68P9)   NHYDROUS (UNII: 9SW4PFD2F   NII: B697894SGQ)   *2JP)   11: 50CF3011KX)   *ATE (UNII: JVL98CG53G)   *)	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
PO SO In W/ HY SO GL SO PO TIT CC SO XA	ATER (UNII: 059Q DIUM FLUORIDI ACTIVE INGRE ATER (UNII: 059Q DRATED SILICA PRBITOL (UNII: 50 YCERIN (UNII: 9D DIUM TRIPOLYF DIUM TRIPOLYF DIUM TRIPOLYF DIUM TRIPOLYF DIUM METHYLENE GI CAMIDOPROPY DIUM METHYL (UNI	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients dients fokoor) (UNII: Y607T4G 06T60A25R) 0C6A3C00X) PHOSPHATE AI LYCOL 400 (UI E (UNII: 15FIX9V L BETAINE (UN COCOYL TAUR NII: TTV12P4NEE DE (UNII: 55X04	edient Name   X2JN0Z) (NITRATE ION - UNII:T   \$74W7) (FLUORIDE ION - UNII:C   Ingredient Name   \$8P9)   NHYDROUS (UNII: 9SW4PFD2F   NII: B697894SGQ)   *2JP)   III: 5OCF3011KX)   *ATE (UNII: JVL98CG53G)   ****	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
PO SO In W/ HY SO GL SO TIT CC SO XA SO SA	ATER (UNII: 059Q DIUM FLUORIDI ACTIVE INGRE ATER (UNII: 059Q DRATED SILICA RBITOL (UNII: 50 YCERIN (UNII: 50	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients FOKOOR) (UNII: Y6O7T4G D6T60A25R) DC6A3C0OX) PHOSPHATE AI LYCOL 400 (UI E (UNII: 15FIX9V L BETAINE (UN COCOYL TAUR MII: TTV12P4NEE DE (UNII: 55X04 JM (UNII: SB8Z1	edient Name   X2JN0Z) (NITRATE ION - UNII:T   \$74W7) (FLUORIDE ION - UNII:C   Ingredient Name   \$8P9)   NHYDROUS (UNII: 9SW4PFD2F   NII: B697894SGQ)   *2JP)   III: 5OCF3011KX)   *ATE (UNII: JVL98CG53G)   ****	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in 1
PO SO In HY SO GL SO FO CC SO SO SO	ATER (UNII: 059Q DIUM FLUORIDI ACTIVE INGRE ATER (UNII: 059Q DRATED SILICA PRITOL (UNII: 50 YCERIN (UNII: PE DIUM TRIPOLYF DIUM TRIPOLYF DIUM TRIPOLYF DIUM METHYLENE GI CAMIDOPROPY DIUM METHYL (UNI DIUM HYDROXII CCHARIN SODIL	Ingre ATE (UNII: RU45 E (UNII: 8ZYQ14 dients FOKOOR) (UNII: Y6O7T4G D6T60A25R) DC6A3C0OX) PHOSPHATE AI LYCOL 400 (UI E (UNII: 15FIX9V L BETAINE (UN COCOYL TAUR MII: TTV12P4NEE DE (UNII: 55X04 JM (UNII: SB8Z1	edient Name   X2JN0Z) (NITRATE ION - UNII:T   \$74W7) (FLUORIDE ION - UNII:C   Ingredient Name   \$8P9)   NHYDROUS (UNII: 9SW4PFD2F   NII: B697894SGQ)   *2JP)   III: 5OCF3011KX)   *ATE (UNII: JVL98CG53G)   ****	980VPU4080)	POTASSIUM NIT	-	50 mg in 1 1.1 mg in

Сс	olor		white	Score			
Sł	nape			Size			
Fla	Flavor MINT			Imprint Code			
Сс	ontains						
<b>D</b> .	alsaging						
P	ackaging						
#	ltem Code	Pacl	kage Description		Marketing Start Date	Marketing End Date	
1	NDC:0135-0551- 04	1 in 1 CARTON			01/02/2002	10/29/2021	
1		113 g in 1 TUBE Product	; Type 0: Not a Cor	mbination			
Μ	larketing l	Information	on				
	Marketing Category	Applicati	on Number or M Citation	lonograph	Marketing Start Date	Marketing End Date	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 5/2024

Haleon US Holdings LLC