#### HISMILE- sodium fluoride gel HISMILE PTY LTD

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## Wonka Flavor Sodium Fluoride Anticavity Toothpaste

### **Active ingredient**

Sodium Fluoride 0.243% (0.14 w/v fluoride ion)

#### **Purpose**

Anticavity

#### Use

Aids in the prevention of dental cavities

#### **Warnings**

Warnings

## When using this product

- Do not swallow
- Do not use in eye area

## Keep out of reach of children under 6 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 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or use as directed by a dentist or doctor.
- Instruct children under 6 years of age in good brushing and rinsing habtis (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

## Inactive ingredients

Water

Sorbitol

Glycerin

Hydrated Silica

Xylitol

Sodium Phosphate

Xanthan Gum

Sodium Lauroyl Sarcosinate

Tetrapotassium Pyrophosphate

1,2-Hexanediol

Cellulose Gum

Sucralose

Lauryl Glucoside

Methyl Diisopropyl Propionamide

Sodium Gluconate

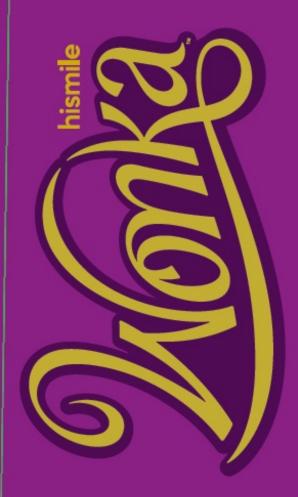
Zinc Lactate

Iron Oxides

## label

CHOCOLATE FLAVOR

# sodium fluoride anticavity toothpaste



Net wt. 2.1 oz (60 g)

Distributed by: Hismile Pty Ltd, Burleigh Waters, QLD 4220 AU.

Formulated in Australia. Made in USA.

www.hismileteeth.com © Hismile Pty Ltd, 2023





PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

# Drug Facts

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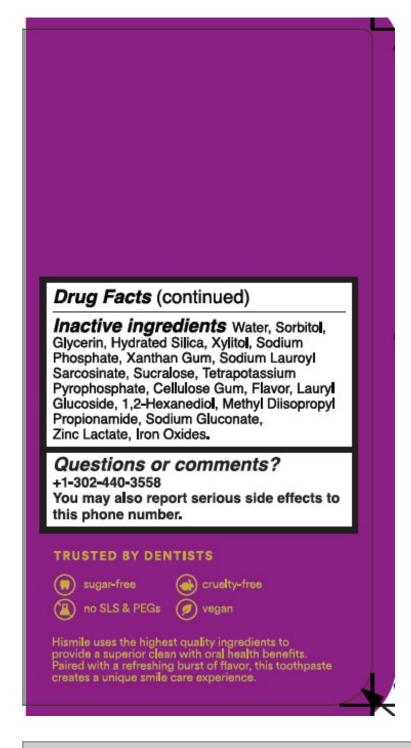
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PLEASE PEEL HERE

WB SHIELD: © & ™ WBEI. (s24) 30101892A



#### **HISMILE**

sodium fluoride gel

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	Source)	NDC:8	33013-325
Route of Administration	DENTAL				
Active Ingredient/Active	Majoty				
Active Ingredient/Active Moiety					
Ingredient Name			<b>Basis of Stren</b>	gth	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION -			CODILIM ELLIODIDE		) 242 a in 100 a

Inactive Ingredients	
Ingredient Name	Strength
FERROUS OXIDE (UNII: G7036X8B5H)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
GLYCERIN (UNII: PDC6A3C0OX)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
ZINC LACTATE (UNII: 2GXR25858Y)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHOCOLATE	Imprint Code		
Contains				

Packaging				
#	Item Code	Item Code Package Description		Marketing End Date
1	NDC:83013- 325-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M021	07/15/2024		

# Labeler - HISMILE PTY LTD (758083252)

Establishment	t		
Name	Address	ID/FEI	<b>Business Operations</b>

Accupac LLC	0	61595175	manufacture(83013-325)

Revised: 7/2024 HISMILE PTY LTD