

**AVON WHITENING ESSENTIALS ORIGINAL COOL MINT- sodium fluoride paste, dentifrice**

**Tai Guk Pharm. Co., Ltd.**

*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.*

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**AVON Whitening Essentials Original Cool Mint**

**Drug Facts**

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**Active Ingredient**

Sodium fluoride 0.243% (0.16% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

helps protect against cavities

**Warnings**

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**Keep out of reach of children.**

Keep out of reach of children under 6 years of age. Do not swallow. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. If an allergic reaction develops, discontinue to use immediately.

**Directions**

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Adults and children 6 years and older	Brush teeth thoroughly after each meal or at least twice a day, or as directed by a dentist and physician. Do not swallow.
Children between 6 and 12 years	To minimize swallowing, use a pea-sized amount and supervise children's brushing and rinsing until good habits are established.
Children under 6 years	Ask a dentist or physician.

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**Inactive Ingredients**

glycerin, hydrated silica, sodium hexametaphosphate, water, PEG-6, flavor, flavor, trisodium phosphate, sodium lauryl sulfate, carrageenan, cocamidopropyl betaine, sodium saccharin, sucralose, xanthan gum, titanium dioxide, mica, charcoal powder, citrus limon(lemon) fruit extract, sodium chloride

1-800-FOR-AVON

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# Principal Display Panel - 156 g Tube Carton

AVON

## Whitening Essentials

FLUORIDE TOOTHPASTE

CAVITY PROTECTION

HELPS WHITEN TEETH - REMOVES SURFACE STAINS

ORIGINAL

COOL MINT

NET WT 5.5 oz (156 g)



## AVON WHITENING ESSENTIALS ORIGINAL COOL MINT

sodium fluoride paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43136-901
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.6 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
HEXASODIUM HEXAMETAPHOSPHATE (UNII: N40N91DW96)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MICA (UNII: V8A1AW0880)	
CITRUS LIMON FRUIT OIL (UNII: 0HNC1J1YED)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

## Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT (Cool)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43136-901-01	1 in 1 CARTON	07/31/2019	
1		156 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	part355	07/31/2019	

**Labeler** - Tai Guk Pharm. Co., Ltd. (689060246)

## Establishment

Name	Address	ID/FEI	Business Operations
Tai Guk Pharma. Co., Ltd.		689060246	manufacture(43136-901)