

DENTREE- sodium fluoride gel, dentifrice
E-SOUP 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.

Drug Facts

Active Ingredient

Sodium fluoride-----0.22%
(1010 ppm of fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities, reducing halitosis, and tooth whitening

Warnings

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 6 years of age and older

Brushless: shake the container before pumping 2-3 times on a toothbrush to brush the teeth or into mouth for close-mouthed, gargle the foam inside the mouth for about 30 seconds. Rinse off the residue with clean water several times to achieve the intended cleanliness.

With Brush: after gargle the foam inside the mouth for about 30 seconds, you may use toothbrush to clean before rinse.

Children under 6 years old

ask a dentist or physician

Other Information

store at room temperature

Inactive Ingredients

allantoin, ginger extract, hydroxyapatite, *Lingusticum wallichii*, mugwort extract, water

Questions or Comments?

call +82(53)584 3320

PRINCIPAL DISPLAY PANEL



DENTREE

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 170-10 1
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.22 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
GINGER (UNII: C5529G5JPQ)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
LIGUSTICUM WALLICHII WHOLE (UNII: 8Y1N3NX2DW)	
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76170-101-50	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/01/2012	

Labeler - E-SOUP Co., Ltd. (557805059)

Establishment

Name	Address	ID/FEI	Business Operations
E-SOUP Co Ltd		557805059	manufacture(76170-101)

Revised: 4/2020

E-SOUP Co., Ltd.