# 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.

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#### **Drug Facts**

#### **Active Ingredient**

Sodium fluoride-----0.22% (1000 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; gurgle 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 gurgle 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, Tribasic Calcium Phosphate, Lingusticum Wallichii Whole, Artemisia princeps leaf, water

#### **Questions or Comments?**

call +82(53)584 3320

### PRINCIPAL DISPLAY PANEL

			Deming Toothpaste
Drug Facts  Active Ingredient Sodium fluoride	E-SOUP NDC 76170-102-02		E-SOUP NDC 76170-102-02
Use aids in the prevention of dental cavities, reducing halitosis, and tooth whitening  Warmings 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 dose-mouthed; gurgle the foam inside the mouth for about 30 seconds. Rinse off the residue with clean	Dentree Red Foaming Toothpaste		Dentree Red Foaming Toothpaste
water severaltimes to achieve the intended cleanliness. With Brush: after gurgle the foam inside the mouth for about 30 seconds, you may use toothbrush to dean before rinse. Children under 6 years old ask a dentist or physician Other Information store at room temperature.	Cavity Prevention Halitosis Reduction Tooth Whitening		Cavity Prevention Halitosis Reduction Tooth Whitening
Inactive Ingredients Allantoin, Ginger, Tribasic Calcium Phosphate, Lingusticum Wallichii Whole, Artemisia princeps leaf, water  Questions or comments? call + 82(53)584 3320  Lot No. / Expiration Date	50ml	Made in Korea	50ml
NDC 76170-102-02 E-SOUP Co., Ltd. Rm 333, R&D Center, Daegu Techno Park venture Factory, 62, Seongseo Gongdan-ro 11-gil, Dalseo-gu, Daegu, KOREA 704-984		8  803802  006131	

sodium fluoride gel, dentifrice

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76170-102

Route of Administration DENTAL

### Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	SODIUM FLUORIDE	0.22 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALLANTO IN (UNII: 344S277G0Z)			
GINGER (UNII: C5529G5JPQ)			
TRIBASIC CALCIUM PHO SPHATE (UNII: 91D9 GV0 Z28)			
LIGUSTICUM WALLICHII WHO LE (UNII: 8 Y1N3NX2DW)			
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	red	Score		
Shape		Size		
Flavor	STRAWBERRY	Imprint Code		
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76170-102- 01	1 in 1 CARTON	12/01/2012	
1		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:76170-102- 02	1 in 1 CARTON	12/01/2012	
2		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:76170-102- 03	1 in 1 CARTON	12/0 1/20 12	
3		100 mL in 1 BOTTLE, PUMP; 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	12/0 1/20 12	

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

Establishment			
Name	Address	ID/FEI	Business Operations
E-SOUP Co., Ltd		557805059	manufacture(76170-102)

Revised: 4/2020 E-SOUP Co., Ltd.