

**PINE SALT 170G- sodium fluoride paste, dentifrice
HANUL TRADING 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.

ACTIVE INGREDIENT

Active Ingredient: SODIUM FLUORIDE (0.22%)

INACTIVE INGREDIENT

Inactive Ingredients: WATER, SORBITOL, HYDRATED SILICA, COCAMDOPROPYL BETAINE, PEG-32, CELLULOSE GUM, SODIUM LAURYL SULFATE, PINUS SYLVESTRIS CONE EXTRACT, FRAGRANCE, ZEOLITE, MENTHOL, SODIUM CHLORIDE, TRANEXAMIC ACID, SODIUM SACCARIN, METHYLPARABEN, SODIUM METHYL COCOYL TAURATE, SODIUM HYDROXIDE, SODIUM BENZOATE, TITANIUM DIOXIDE, CI 47005, CI 42090

PURPOSE

Purpose: Anticavity

WARNINGS

Warnings: Keep out of the 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.

KEEP OUT OF REACH OF CHILDREN

Keep out of the reach of children under 6 years of age.

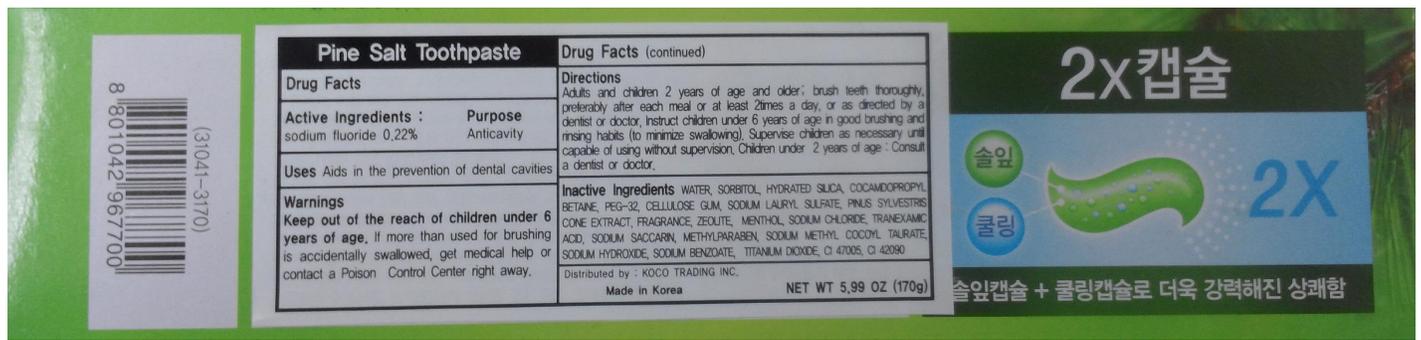
USE

USE: Aids in the prevention of dental cavities

Directions

Directions: Adults and children 2 years of age and older; brush teeth thoroughly, preferably after each meal or at least 2 times a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



PINE SALT 170G

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69642-1100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.374 g in 170 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69642-1100-1	170 g in 1 CARTON; 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	02/01/2015	

Labeler - HANUL TRADING CO., LTD. (689512982)

Registrant - HANUL TRADING CO., LTD. (689512982)

Establishment

Name	Address	ID/FEI	Business Operations
HANUL TRADING CO., LTD.		689512982	repack(69642-1100)

Establishment

Name	Address	ID/FEI	Business Operations
AMOREPACIFIC		687995683	manufacture(69642-1100)

Establishment

Name	Address	ID/FEI	Business Operations
KOCO TRADING CO., INC.		079457993	wholesale drug distributor(69642-1100)

Revised: 6/2015

HANUL TRADING CO., LTD.