

SALTRAIN CLEAN BREATH- sodium fluoride mouthwash
K.Boeun Pharmaceutical 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.

Sodium Flouride

For dental care

Keep out of reach of children

Put an appropriate amount in your mouth, gargle for 30 seconds, spit out, and brush your teeth by brushing

Do not swallow

Keep out of reach of children under 6 years old.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Concentrated Glycerin, Polyethylene Glycol 1500, Polysorbate 20, Xylitol, Sodium Chloride, I-Menthol, Mentha Oil, Sage Extract, Aloe Extract, Eucalyptus Extract, Water

For dental use only

Product Name: Clean breath Mouthwash
Volume: 12ml/0.40oz X 15pc (180ml/6.08oz)

Drug Facts

Active Ingredient

Sodium Fluoride 0.02%

Purpose

Anticavity

Uses ■ Aids in the prevention of dental cavities.

Warnings

- 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

- Put an appropriate amount in your mouth, gargle for 30seconds, spit out, and brush your teeth by brushing.
- Do not swallow.

Other Information

- Store in an airtight container at room temperature
- Date of use : 24 months from the date of manufacture

Inactive Ingredients

Water, Peppermint Oil, L-Menthol, Xylitol, Sodium Chloride, Polysorbate 20, Polyethylene Glycol 1500, Concentrated Glycerin, Eucalyptus Extract, Aloe Extract, Sage Extract, Chamomile Extract

Questions or Comments?

email : info@beyondi.kr

[DISTRIBUTED BY]

BEYOND.i company

[MANUFACTURER BY]

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SALTRAIN

GRAY SALT MOUTHWASH

SALTRAIN CLEAN BREATH

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74724-0020
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.02 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74724-0020-1	15 in 1 BOX	11/01/2020	
1		12 mL in 1 POUCH; 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	11/01/2020	

Labeler - K.Boeun Pharmaceutical Co.,Ltd. (695674074)

Registrant - K.Boeun Pharmaceutical Co.,Ltd. (695674074)

Establishment

Name	Address	ID/FEI	Business Operations
K.Boeun Pharmaceutical Co.,Ltd.		695674074	manufacture(74724-0020)

Revised: 11/2020

K.Boeun Pharmaceutical Co.,Ltd.