

**SALTRAIN TOOTH- sodium monofluorophosphate paste**  
**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 Monofluorophosphate

For dental care

Keep out of reach of children

Apply an appropriate amount to your toothbrush and brush your teeth by brushing

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.

Precipitated Calcium Carbonate, Dibasic Calcium Phosphate, Aminocaproic Acid, Aluminium Chlorohydroxy Allantoinate, D-Sorbitol Solution, Concentrated Glycerin, Polyethylene Glycol 1500, Xanthangum, Sodium Cocoyl Glutamate, Silicon Dioxide, Titanium Oxide, Enzymatically Modified Stevia, Xylitol, Sodium Chloride, Ascorbic Acid, Mentha Oil, l-Menthol, Spearmint Oil, Water

For dental use only

# SALTRAIN

## SALTRAIN TOOTH

sodium monofluorophosphate paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74724-0021
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.4 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>AMINOCAPROIC ACID</b> (UNII: U6F3787206)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74724-0021-1	100 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2020	

**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(74724-0021)

Revised: 11/2020

K.Boeun Pharmaceutical Co.,Ltd.