

**PREMIERPRO FLUORIDE TOOTH- sodium monofluorophosphate paste, dentifrice SVS, LLC (DBA S2S Global)**

*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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Active Ingredient: Sodium Monofluorophosphate (0.76%)

Purpose: Anticavity

Uses: Aids in the prevention of dental cavities

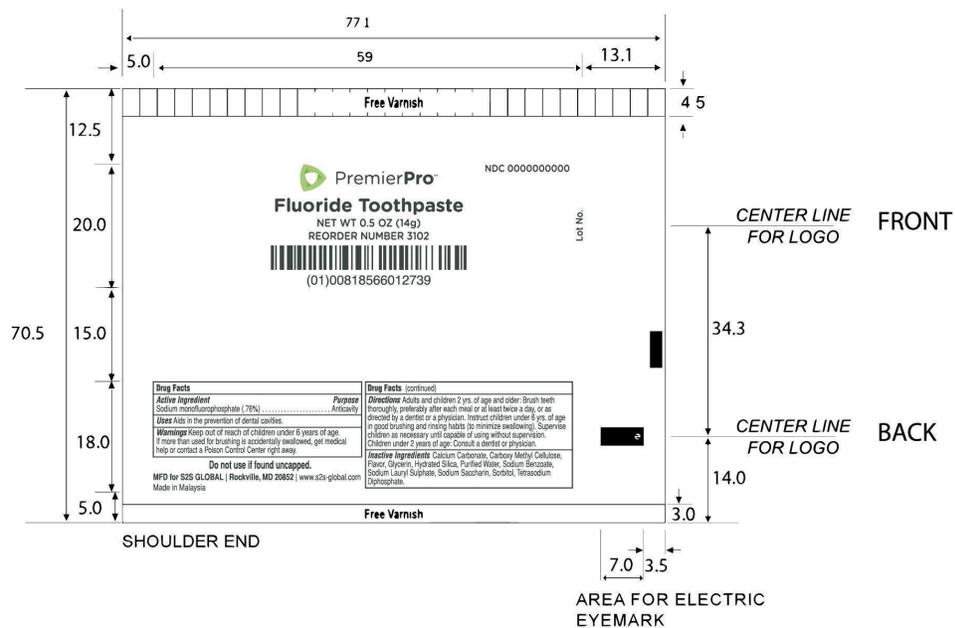
For external use only.

Keep out of reach of children under six years of age

If more than used for brushing is accidentally swallowed, get medical help or contact a poison control center right away

Adults and children of two years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a doctor. Instruct children under six years of age in good brushing and rinsing habit (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: consult a dentist or physician.

Calcium Carbonate, Carboxymethylcellulose Sodium, Flavour, Glycerin, Purified Water, Sodium Benzoate, Sodium Lauryl Sulfate, Hydrated Silica, Saccharin Sodium, Sorbitol, Tetrasodium Diphosphate.



sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69392-001
<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	0.10 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 100-200 MPAS AT 1%) (UNII: 99H65D77XY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69392-001-01	14 g in 1 TUBE		
2	NDC:69392-001-02	24 g in 1 TUBE		
3	NDC:69392-001-03	42 g in 1 TUBE		
4	NDC:69392-001-04	78 g in 1 TUBE		
5	NDC:69392-001-05	85 g in 1 TUBE		
6	NDC:69392-001-06	130 g in 1 TUBE		
7	NDC:69392-001-07	198 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/01/2015	

**Labeler** - SVS, LLC (DBA S2S Global) (831375089)

