SKYLINE HERBALS- sodium monofluorophosphate paste, dentifrice
SKYLINE HERBALS PRIVATE LIMITED

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.

SKYLINE Fluoride Toothpaste

Drug Facts

Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)

Purpose

Anticavity Toothpaste

Use

aids in the prevention of dental cavities

Warning

- Keep out of reach of children under 6 years of age

Warning

- If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control center immediately

Directions

- Do not swallow
- Supervise children as necessary until capable of using without supervision
- Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing)
- **Adults and children 6 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 physician
- **Children under 6 years of age:** Do not use unless directed by a dentist or physician

Other Information

- Store at 59°-86°F (15°-30°C)
- Avoid excessive heat

Inactive Ingredients

Calcium Carbonate, Water, Sorbitol, Hydrated Silica, Sodium Lauryl Sulfate, Sodium Carboxymethyl Cellulose, Flavor, Sodium Saccharin, Sodium Methyl Paraben, Sodium Propyl Paraben

PRINCIPAL DISPLAY PANEL - 43 g Tube Carton

SKYLINE HERBALS

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80239-9138
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	

PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80239-9138-6	43 g in 1 TUBE; Type 0: Not a Combination Product	07/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/23/2019	

Labeler - SKYLINE HERBALS PRIVATE LIMITED (877566114)

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