ASTONEA -SODIUM FLUORIDE- sodium floride paste, dentifrice ASTONEA LABS 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.

astonea -sodium fluoride

Drug Facts

Active ingredient

Sodium Fluoride 0.22% w/w

Purpose

Anticavity Toothpaste

Use

aids in the prevention of dental cavities

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 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

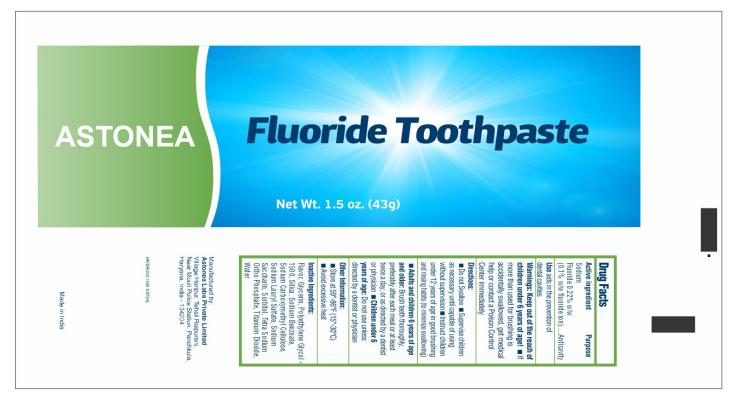
Other Information

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

Inactive Ingredients

Flavor, Glycerin, PEG-1500, Silica, Sodium Benzoate, Sodium Carboxymethyl Cellulose, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Tetra Sodium Pyrophosphate, Titanium Dioxide, Water

PRINCIPAL DISPLAY PANEL - 43 g Tube Carton



ASTONEA -SODIUM FLUORIDE

sodium floride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-091

Route of Administration DENTAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 0.22 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-091- 38	43 g in 1 TUBE; Type 0: Not a Combination Product	01/15/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/15/2015	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

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