

ASTONEA -SODIUM FLUORIDE- sodium fluoride paste, dentifrice
ASTONEA LABS PRIVATE LIMITED

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

Fluoride Toothpaste

Net Wt. 1.5 oz. (43g)

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.22% w/w (1.1% w/w fluoride ion).... Anticavity	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 flossing 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, Polyethylene Glycol-1500, Silica, Sodium Benzoate, Sodium Carboxymethyl Cellulose, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Tera Sodium Citrate Phosphate, Titanium Dioxide, Water	

Manufactured by:
Astona Labs Private Limited
Village Harpur, Tehsil Rajpura,
Near Mouli Police Station, Panchkula,
Haryana, India - 134204

HMDUS 1165-05(19)

Made in India

ASTONEA -SODIUM FLUORIDE

sodium fluoride 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: 15F1X9V2JP)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

SODIUM PYROPHOSPHATE (UNII: O352864B8Z)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item 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 Drug	M022	01/15/2015	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 6/2024

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