

ASTONEA -SODIUM FLUORIDE- sodium fluoride 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

Fluoride Toothpaste

Net Wt. 1.5 oz. (43g)

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.22% w/w (0.1% 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 rinsing habits (to minimize swallowing)
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Other Information:

- Store at 59° -98°F (15° -30°C)
- Avoid excessive heat

Inactive Ingredients:

Flavor: Glycerin, Polyethylene Glycol - 150, Silica, Sodium Benzoate, Sodium Carboxymethyl Cellulose, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Tetra Sodium Ortho Phosphate, Titanium Dioxide, Water

Manufactured by:
Astomem Labs Private Limited
 Village Harpur, Tehsil Rappurani,
 Near Mujil Police Station, Panchoikula,
 Haryana, India - 134204

HEMENDUS 116-05761

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:Q80VPU408O)	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: 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 final	part355	01/15/2015	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 12/2022

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