

**FLUORIDE TOOTHPASTE- sodium monofluorophosphate paste, dentifrice**  
**NEW WORLD HEALTHCARE 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.*

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**SMARTH-Good morning**

**Drug Facts**

**Active ingredient**

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

**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**

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**

New  
SMARTH



SMARTH®

Fluoride Toothpaste

Net Wt. 1.5 oz. (43g)

Reorder No.  
91386

**Manufactured By:**  
New World Healthcare Pvt Ltd,  
State Highway, Unjha-384170  
Dist. Mehsana, N. Gujarat  
Made in India

Drug Facts	
Active ingredient	Purpose
Sodium monofluorophosphate 0.76% (0.1% w/w fluoride ion), ... Anticavity Toothpaste	
Uses aids in the prevention of dental cavities	
<b>Warnings:</b> 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.	
<b>Directions:</b>	
<ul style="list-style-type: none"> <li>■ 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)</li> <li>■ 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</li> </ul>	
<b>Other information:</b>	
<ul style="list-style-type: none"> <li>■ Store at 20°-25° (68°-77°)</li> <li>■ Avoid excessive heat</li> </ul>	
<b>Inactive ingredients:</b>	
Calcium Carbonate, Water, Sorbitol, Hydrated Silica, Sodium Lauryl Sulfate, Sodium Carboxymethyl Cellulose, Flavor, Sodium Saccharin, Sodium Methyl Paraben and Sodium Propyl Paraben	

## FLUORIDE TOOTHPASTE

sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72423-1073
<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	0.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	

<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>METHYL PARABEN SODIUM</b> (UNII: CR6K9C2NHK)	
<b>PROPYL PARABEN SODIUM</b> (UNII: 625NNB0G9N)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72423-1073-6	43 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/01/2018	

**Labeler** - NEW WORLD HEALTHCARE PRIVATE LIMITED (873672074)

**Establishment**

Name	Address	ID/FEI	Business Operations
NEW WORLD HEALTHCARE PRIVATE LIMITED		873672074	manufacture(72423-1073)

Revised: 7/2018

NEW WORLD HEALTHCARE PRIVATE LIMITED