

MORNING FRESH- sodium fluoride paste
Patcos Cosmetics (India) 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.

Toothpaste

Active Ingredient

Sodium Fluoride 0.22 %

Purpose: Anticavity

Use

- Aids in the prevention of dental cavities.

Inactive Ingredient

Calcium carbonate, Carboxymethylcellulose sodium, Flavour, Hydrated silica, Potassium nitrate, Purified water, Saccharin sodium, Sodium benzoate, Sodium lauryl sulfate, Sorbitol

Dosage and Administration

Directions:

- **Adults and children 2 years and older** *Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician.*
- **Children under 6 years** *To minimize swallowing, use a pea sized amount and supervise brushing until good habits are established.*
- **Children under 2 years** *Ask a dentist or physician.*

Indications and Usage

- The prevention of dental cavities.

Warnings

- If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.

Keep out of reach of children.

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

Principal Display Panel

Patcos Toothpaste

Patcos Toothpaste 1.jpg

Reorder No. 4872
 Net Wt. 1.5 oz (43g)
 NDC# 68121-174-01
 N. C. No: DD/COS/DD/C/340

**Morning
 Fresh**

Flouride Toothpaste



patcos cosmetics
 (India) Pvt.Ltd.

Lot #:

Exp. Date: mm/dd/yyyy FPO

Made in India
 Manufactured by:
 Patcos Cosmetics Pvt. Ltd.
 659/A, Kevdi Road,
 Dabhel Daman
 396 210

Drug Facts	Drug Facts (continued)
Active Ingredient Purpose Sodium fluoride 0.22% Anticavity	Directions Adults and children 2 yrs. and older • Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician.
Use Aids in the prevention of dental cavities.	Children under 6 yrs. • To minimize swallowing use a pea sized amount and supervise brushing until good habits are established.
Warnings Keep out of reach of children under 6 years of age • If you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center immediately.	Children under 2 yrs. • Ask a dentist or physician.
	Inactive Ingredients • Calcium carbonate, Carboxymethylcellulose sodium, Flavor, Hydrated silica, Potassium nitrate, Purified water, Saccharin sodium, Sodium benzoate, Sodium lauryl sulfate, Sorbitol.

MORNING FRESH

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 121-174
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0K00R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68121-174-01	43 g in 1 TUBE; Type 0: Not a Combination Product	05/14/2014	
2	NDC:68121-174-02	78 g in 1 TUBE; Type 0: Not a Combination Product	05/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/14/2014	

Labeler - Patcos Cosmetics (India) Private Limited (916169451)

Establishment

Name	Address	ID/FEI	Business Operations
Patcos Cosmetics (India) Private Limited		675973979	manufacture(68121-174)

Revised: 12/2017

Patcos Cosmetics (India) Private Limited