

## **PROSYS 5000- sodium fluoride paste, dentifrice**

### **Benco Dental**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).*

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## **ProSys 5000**

### **DRUG FACTS**

#### ***Active Ingredient***

1.1% Neutral Sodium Fluoride

***Inactive Ingredients:*** Filtered Water, Sorbitol, Hydrated Silica, Glycerin, PEG, Carboxymethylcellulose, Xylitol, Monosodium Phosphate, Titanium Dioxide, Mint, Sodium Saccharin, Tri-Calcium Phosphate.

#### ***Indications***

PRO-SYS Professional is a self-applied dentifrice for - prevention of tooth decay, orthodontic decalcification - and hypersensitivity

#### ***Warnings***

- **Do not swallow • For topical use only**
- **As with all medications, keep out of reach of children**

#### ***Directions: Use As Directed***

This prescription dentifrice is recommended for adults and pediatric patients six years and older.

- Apply a thin ribbon of PRO-SYS Professional along the length of the toothbrush no more than "pea size" total dose. Brush for two minutes.
- After brushing:  
ADULTS-Expectorate; do not eat or drink for 30 minutes.  
CHILDREN SIX YEARS OF AGE OR OLDER-Expectorate and rinse mouth with water.
- Use at bedtime in place of your regular toothpaste or as directed by your dental professional.

For more information on the entire family of PRO-SYS oral care products, visit [www.PRO-SYS.com](http://www.PRO-SYS.com).

## **Package Label - ProSys 5000**

DENTIST RECOMMENDED

**PRO-SYS**

PROFESSIONAL

ANTI-CAVITY FLUORIDE TOOTHPASTE

VANILLA MINT 4 OZ. RX ONLY [4710-501]

WWW.PRO-SYS.COM

Distributed by

**BencoDental**

**800.GO.BENCO • [benco.com](http://benco.com)**

295 CentralPoint Blvd., Pittston, PA 18640



Product Type		HUMAN PRESCRIPTION DRUG		Item Code (Source)		NDC:66975-501	
Route of Administration		ORAL					
Active Ingredient/Active Moiety							
Ingredient Name				Basis of Strength		Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)				SODIUM FLUORIDE		1.1 g in 100 g	
Inactive Ingredients							
Ingredient Name						Strength	
WATER (UNII: 059QF0KO0R)							
SORBITOL (UNII: 506T60A25R)							
HYDRATED SILICA (UNII: Y6O7T4G8P9)							
GLYCERIN (UNII: PDC6A3C0OX)							
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)							
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)							
XYLITOL (UNII: VCQ006KQ1E)							
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)							
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)							
MINT (UNII: FV98Z8GITP)							
SACCHARIN SODIUM (UNII: SB8ZUX40TY)							
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)							
Product Characteristics							
Color				Score			
Shape				Size			
Flavor		VANILLA (MINT)		Imprint Code			
Contains							
Packaging							
#	Item Code	Package Description		Marketing Start Date		Marketing End Date	
1	NDC:66975-501-04	112 g in 1 TUBE; Type 0: Not a Combination Product		10/13/2023			
Marketing Information							
Marketing Category		Application Number or Monograph Citation		Marketing Start Date		Marketing End Date	
unapproved drug other				10/13/2023			

**Labeler -** Benco Dental (015108087)

