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.

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.

Package Label - ProSys 5000

DENTIST RECOMMENDED

PRO-SYS

PROFESSIONAL

ANTI-CAVITY FLUORIDE TOOTHPASTE

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

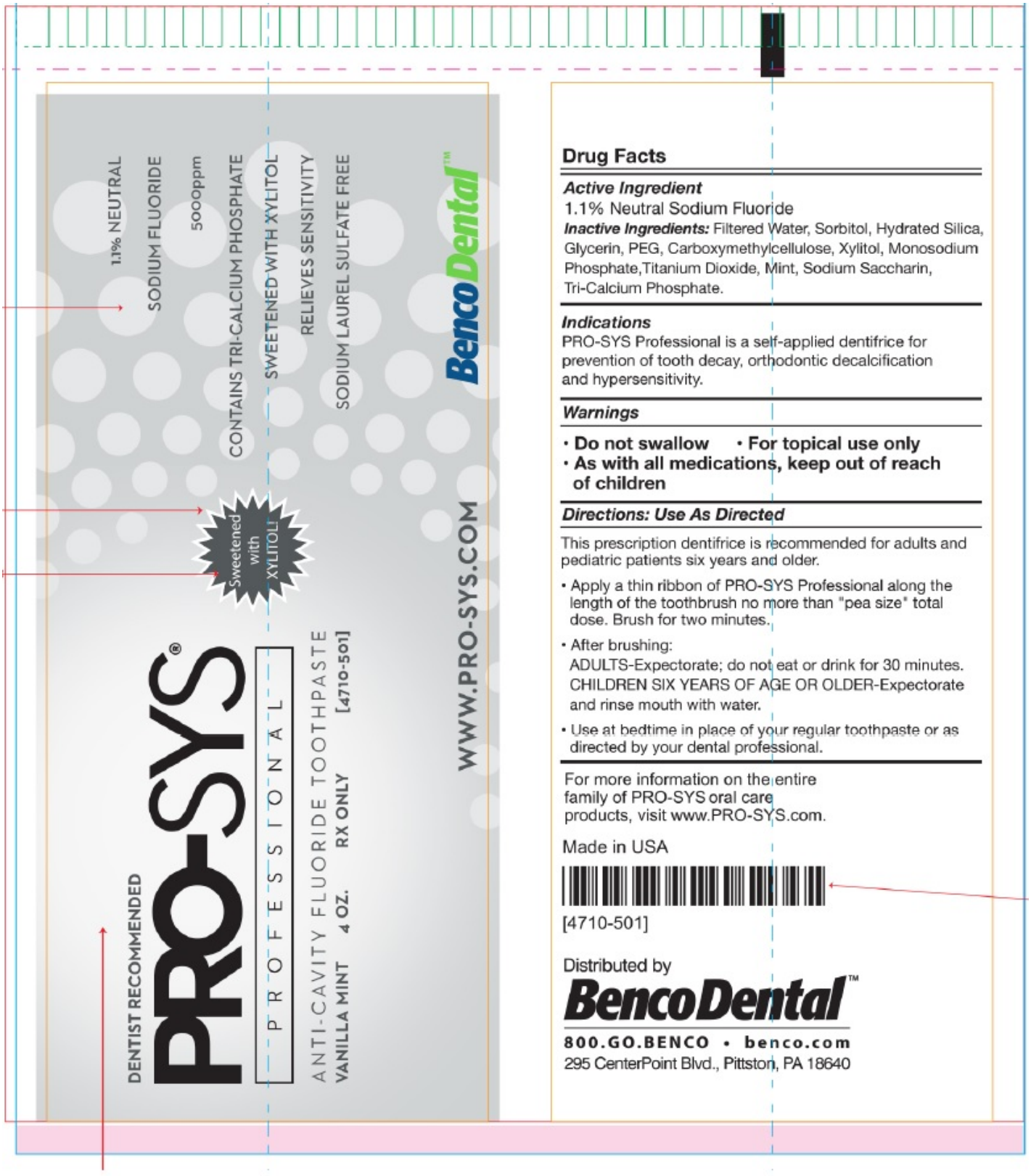
WWW.PRO-SYS.COM

Distributed by

BencoDental

800.GO.BENCO • benco.com

295 CentralPoint Blvd., Pittston, PA 18640



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PROSYS 5000

sodium fluoride paste, dentifrice

Product Information

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: 3WQ0SDW1A)	
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)

Registrant - Benco Dental (015108087)

Revised: 12/2024

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