

**PRO-DEN RX- stannous fluoride rinse**  
**Den-mat Holdings, Llc**

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**ProDenRx**

**Drug Facts**

**Active Ingredient**

Stannous Fluoride 0.63% w/w  
(0.19% w/v fluoride ion)

**Purpose**

anticavity

**Uses**

- Aids in the prevention of dental caries (cavities).
- Control of perio infection
- Relief of dentin sensitivity

**Warnings**

**When using this product** it may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

**Keep out of reach of children.** If more than used for rinsing s accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Do not use before mixing with water
- Use immediately after preparing the rinse

**Adults and children 6 years of age and older:**

- Use as directed by a dental professional
- Use once a day after brushing your teeth with a toothpaste or as directed by your dentist
- Remove cap and seal and replace with pump
- Rotate spout counter clockwise to extend
- Depress pump until medicine comes to the tip of the pump
- Put 1/8 oz. (approx. 2 pump strokes) of concentrated Pro-DenRx Rinse into the provided mixing vial
- Add water to 1 oz. line on mixing vial
- Tightly snap on the cap and shake well

- Vigorously swish between your teeth 1/2 of mixture for one minute and then spit out
- Repeat procedure with remaining mixture
- Rinse mixing vial with water after use
- Do not swallow the rinse
- Do not eat or drink for 30 minutes after rinsing

**Children 6 to 12 years of age:**

- Instruct children in good rinsing habits (to minimize swallowing)
- Supervise children as necessary until capable of using without supervision

**Children under 6 years of age:**

- Consult a dentist or doctor For home irrigation
- Prepare 1 oz. of Pro-DenRx Rinse as described above
- Pour into irrigator reservoir, add 4 oz. of water and mix thoroughly
- Use irrigator as directed
- Rinse irrigator with water after use

**Other information**

For your protection, do not use if seal under the cap is broken or missing.

**Inactive ingredients**

flavor, glycerin, methylparaben, propylparaben, sodium saccharin

**Principal Display Panel - Carton Label**

NDC 59883-720-08

pro-denRx<sup>®</sup>

dye  
free  
rinse

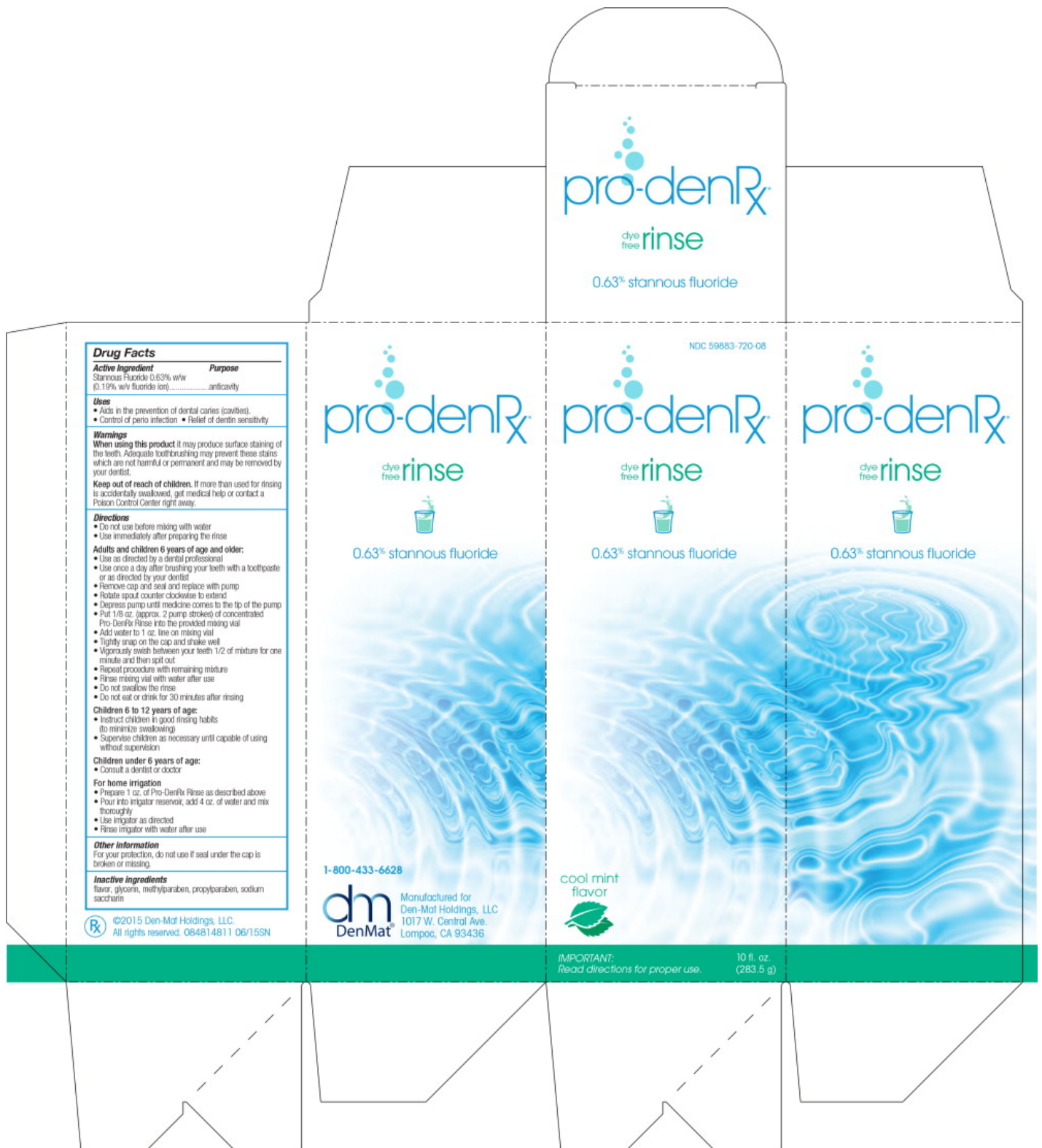
0.63 % stannous fluoride

cool mint  
flavor

**IMPORTANT:**

Read directions for proper use.

10 fl. oz.  
(283.5 g)



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**Drug Facts (continued)**

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**For home irrigation**  
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• Use irrigator as directed  
• Rinse irrigator with water after use

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**Inactive ingredients**  
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1-800-433-6628

dm DenMat®  
Manufactured by Den-Mat Holdings, LLC  
1017 W. Central Ave.  
Longport, CA 93436

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IMPORTANT: Read directions for proper use. 10 fl. oz. (283.5 g)

## PRO-DEN RX

stannous fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59883-720
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>STANNOUS FLUORIDE</b> (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.53 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (MINT)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-720-08	1 in 1 CARTON	10/31/2008	
1		283.5 g in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	10/31/2008	

**Labeler** - Den-mat Holdings, Llc (809857704)

Revised: 11/2023

Den-mat Holdings, Llc