PRO-DEN RX- sodium fluoride rinse
Den-Mat Holdings, Llc

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.

2% Fluoride Rinse - Den-Mat

Indications and Usage

For topical application to aid in the protection against dental caries. Neutral pH is especially safe for crowns and restorations.

Dosage and Administration

Dispense ½ oz. (approx. 1 pump) of Pro-DenRx 2.0% Neutral Sodium Fluoride Solution into the provided mixing cup. Instruct patient to rinse vigorously for 30 seconds with ½ oz. of the solution around and between teeth, then expectorate. For maximum benefit repeat the rinse procedure with an additional ½ oz. of solution. Pro-DenRx 2.0% Neutral Sodium Fluoride Solution may also be applied full strength, with cotton pledgets, to teeth isolated with cotton rolls.

Recommended Frequency

Do not exceed four (4) treatments per year.

Contraindications

Hypersensitivity to fluoride.

Warnings and Precautions

For Professional Office Use Only. This product is not intended for home or unsupervised consumer use. Do not swallow. Keep out of reach of children. Not recommended for children under the age of 6. Limited to topical use in the mouth only.

Adverse Reactions

The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

Caution

Federal law prohibits dispensing without a prescription.

Overdosage

Accidental ingestion of large amounts of fluoride can cause: nausea, vomiting, abdominal pain, diarrhea, stupor and/ or weakness (usually within 30 minutes). These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight (less than 23 mg fluoride/lb body weight) has been ingested, give calcium (milk) orally to relieve symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight (more than 23 mg fluoride/lb body weight) has been ingested, induce vomiting, give calcium (i.e., milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical

assistance. For accidental ingestion of more than 15 mg fluoride/kg body weight (i.e., more than 6.9 mg fluoride/lb body weight) induce vomiting, transport and admit immediately to a hospital facility.

Ingredients

Water, Sodium Fluoride, Flavor, PEG-40 Hydrogenated Castor Oil, Sodium Benzoate, Disodium Phosphate, Sodium Saccharin, Methylparaben, Sodium Phosphate, Yellow #10, Blue #1.

How Supplied/Storage and Handling

2.0% Neutral Sodium Fluoride (0.9% Fluoride Ion) oral solution supplied in a plastic bottle with child-resistant closure containing 64 fl. oz. (1.89 L). Store at room temperature. Protect from freezing. Do not store in direct sunlight.

Rx Only

Revised: 12/2017

1-800-433-6628

Reorder Number: 2037MTDT

Manufactured for

Den-Mat Holdings, LLC

1017 W. Central Ave.

Lompoc, CA 9343611

Principal Display Panel - 64 fl. oz. Bottle Label

NDC 59883-911-64

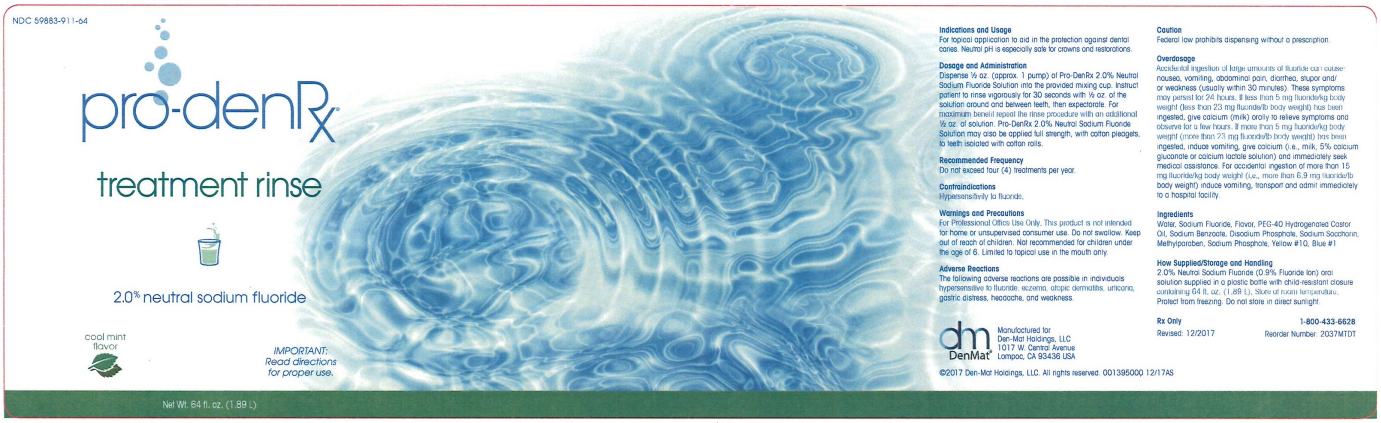
treatment rinse

2.0% neutral sodium fluoride

cool mint flavor

IMPORTANT:
Read directions
for proper use.

Net Wt. 64 fl. oz. (1.89 L)



PRO-DEN RX

sodium fluoride rinse

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59883-911
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	MINT (MINT)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59883-911-64	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/21/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/21/2008	

Labeler - Den-Mat Holdings, Llc (809857704)