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.

Description:

Pro-DenRx ® Neutral Sodium Fluoride Rinse is a neutral, aqueous solution.

Active Ingredient:

Sodium Fluoride 0.2% w/w (0.09% w/w fluoride ion).

Inactive Ingredients:

Purified water, Cetyl Pyridinium Chloride, citric acid, potassium sorbate, sucralose, flavor and Sodium Hydroxide.

Clinical Pharmacology:

Sodium fluoride when used topically promotes remineralization, increases resistance of teeth to acid dissolution, and impedes the cariogenic microbial process.

Indications and Usage:

Aids in the prevention of dental caries. May be used more than once a week if recommended by your dentist. Pro-DenRx ® Rinse is ready to use, convenient and thus increases compliance.

Weekly rinsing with a neutral 0.2% sodium fluoride solution protects against dental cares in adults and children. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis.

Contraindications:

Do not use in children under age 6 years unless recommended by a dentist or physician.

Warnings:

PLEASE KEEP OUT OF REACH OF CHILDREN. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away. READ DIRECTIONS CAREFULLY BEFORE USING.

Precautions:

General: Not for systemic treatment. DO NOT SWALLOW.

Adverse Reactions:

NONE

Overdosage:

Swallowing a normal treatment dose (approximately 9 mg. of fluoride) is not harmful.

Dosage and Administration:

Adults and children over age 6 years: Rinse once a week, preferably at bedtime, after thoroughly brushing and flossing teeth. Rinse more often if your dentist recommends additional therapy based on your diagnosis. Pour 10 ml (2 teaspoons) of Pro-DenRx® 0.2% Sodium Fluoride Rinse into the graduated cup using the markings on its side. Swish vigorously around and between the teeth for one minute, then spit out. DO NOT SWALLOW. For maximum benefit, do not eat, drink, or rinse mouth for at least 30 minutes after use. Children 6 to 12 years old: Supervise while using this product. Children Under 6 years old: Consult your dentist or doctor before using.

How Supplied:

For home use: Plastic bottle containing 16 fl. oz. (473 ml) Cool Mint: NDC 59883-920-16.

RX only:

Storage: Store at Room Temperature

Reorder 1-800-433-6628
Manufactured for
Den-Mat Holdings, LLC 1017 W. Central Ave.
Lompoc, CA 93436

Principal Display Panel - Bottle Label

NDC 59883-920-16

pro-denRx®

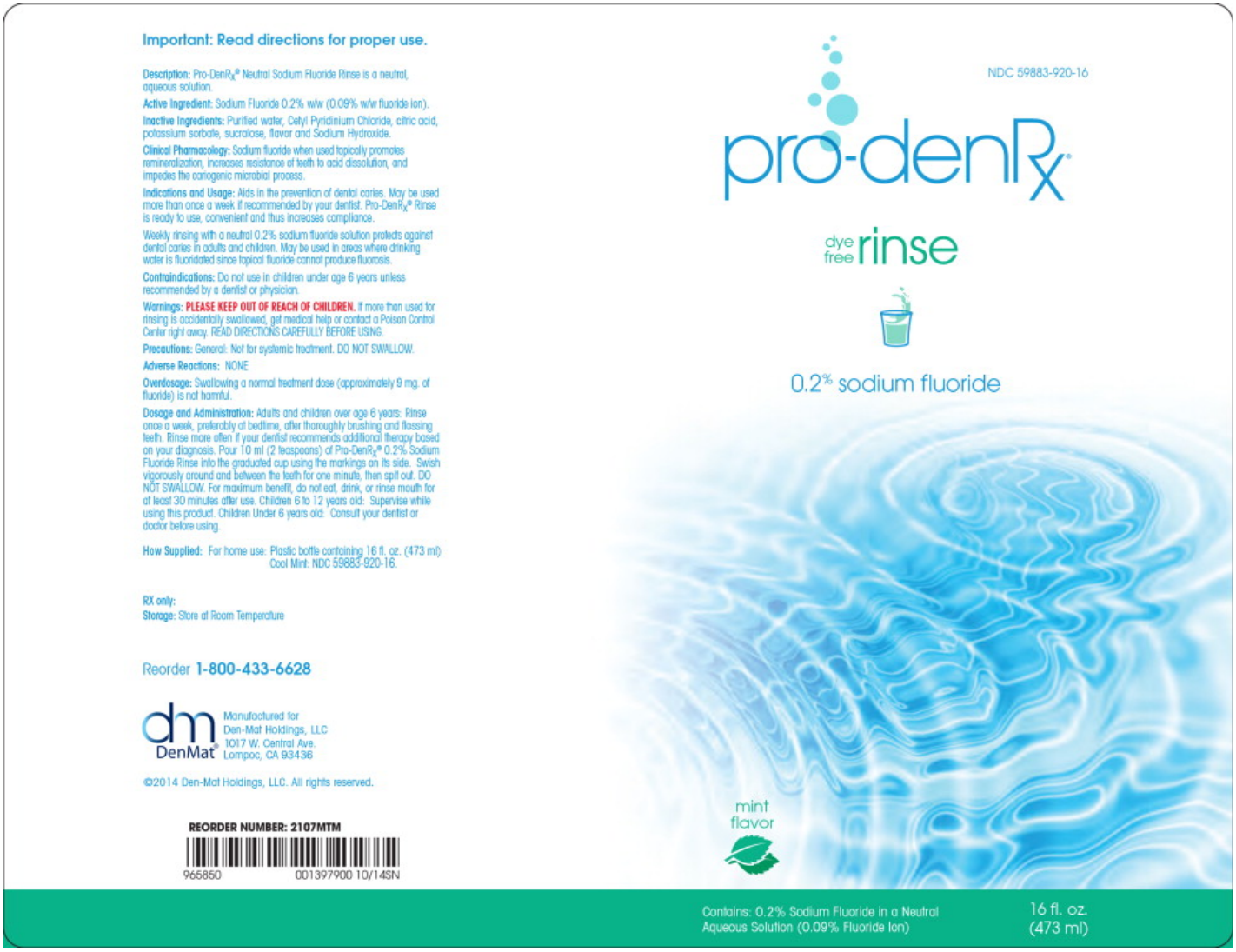
dye
free
rinse

0.2% sodium fluoride

mint
flavor

Contains: 0.2% Sodium Fluoride in a Neutral
Aqueous Solution (0.09% Fluoride Ion)

16 fl. oz.
(473 ml)



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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PRO-DEN RX

sodium fluoride rinse

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59883-920
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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:59883-920-16	473 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	

PRO-DEN RX

sodium fluoride rinse

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59883-922
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-922-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/21/2008	12/31/2014

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/21/2008	12/31/2014

Labeler - Den-mat Holdings, Llc (809857704)

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