PRO-DEN RX- sodium fluoride gel
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:

A homecare, self-applied topical fluoride treatment containing 1.1% Neutral Sodium Fluoride (5000 ppm F). Daily use aids in the prevention of dental caries (decay).

Active Ingredients:

Neutral Sodium Fluoride 1.1% w/w (5000 ppm F).

Inactive Ingredients:

Carboxymethyl cellulose sodium, flavor, phosphoric acid, purified water, sodium hydroxide and sucralose.

Clinical Pharmacology:

Applying preparations containing high fluoride concentrations on a regular basis increases the fluoride ion levels in tooth enamel and improves tooth resistance to acid dissolution.

Indications and Usage:

A homecare, self-applied topical fluoride treatment. Aids in the prevention of dental caries (decay).

Contraindications:

Do not use in children under 6 unless recommended by a dentist.

Warnings:

KEEP OUT OF REACH OF CHILDREN. Children under 6 years old: The potential for fluorosis from repeated swallowing is possible; therefore, children under 6 years old should use only if ordered by dentist and carefully supervised by parent.

Precautions:

Limited to topical use in mouth only. **DO NOT SWALLOW.**

Overdosage:

Swallowing a normal treatment dose (approximately 2 mg of fluoride) is not harmful.

Store at Room Temperature

Dosage and Administration:

Apply daily at bedtime, in place of your regular toothpaste or more often if your dentist recommends

additional therapy based on your diagnosis. Cover brush head with Pro-DenRx 1.1% Neutral Sodium Fluoride Gel and brush around all tooth surfaces and gum line for at least two minutes. Spit out gel. Adults: Wait 30 minutes before rinsing mouth. Children under 12: Rinse mouth thoroughly immediately after use.

When using a mouthpiece or applicator, cover the inner surface with gel. Place applicator in mouth and bite down lightly for at least one minute. Remove applicator and rinse mouth. Clean applicator with cold water.

How Supplied:

Net Wt. 2 oz. (56 g) tube in a box.

Cool Mint: NDC 59883-824-02

Reorder **1-800-433-6628**

Reorder Number: 2240MTM 965918

Manufactured for

Den-Mat Holdings, LLC

1017 W. Central Ave.,

Lompoc, CA 93436

Principal Display Panel - Carton Label

NDC 59883-824-02

pro-denRx ®

aqueous gel

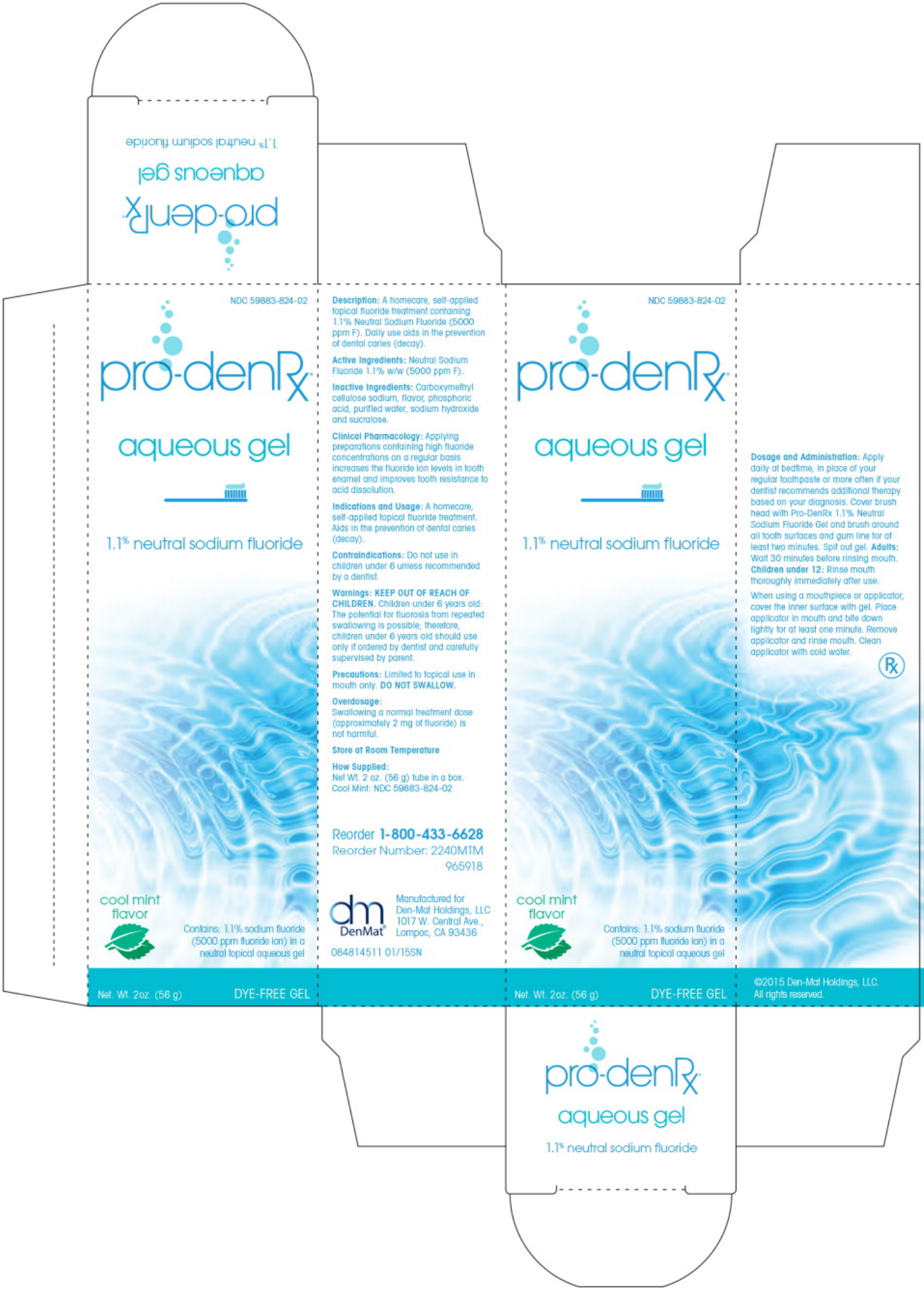
1.1% neutral sodium fluoride

cool mint
flavor

Contains: 1.1% sodium fluoride
(5000 ppm fluoride ion) in a
neutral topical aqueous gel

Net Wt. 2oz. (56 g)

DYE-FREE GEL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pro-denRx
NDC 59883-824-02
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aqueous gel
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Store at Room Temperature
How Supplied:
Net Wt. 2 oz. (56 g) tube in a box.
Cool Mint: NDC 59883-824-02
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DenMat
Manufactured for Den-Mat Holdings, LLC 1017 W. Central Ave., Lompoc, CA 93436
084814511 01/15SN
Dosage and Administration: Apply daily at bedtime, in place of your regular toothpaste or more often if your dentist recommends additional therapy based on your diagnosis. Cover brush head with Pro-DenRx 1.1% Neutral Sodium Fluoride Gel and brush around all tooth surfaces and gum line for at least two minutes. Spit out gel. Adults: Wait 30 minutes before rinsing mouth. Children under 12: Rinse mouth thoroughly immediately after use.
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Rx
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pro-denRx
aqueous gel
1.1% neutral sodium fluoride

Principal Display Panel - Tube Label

NDC 59883-824-02

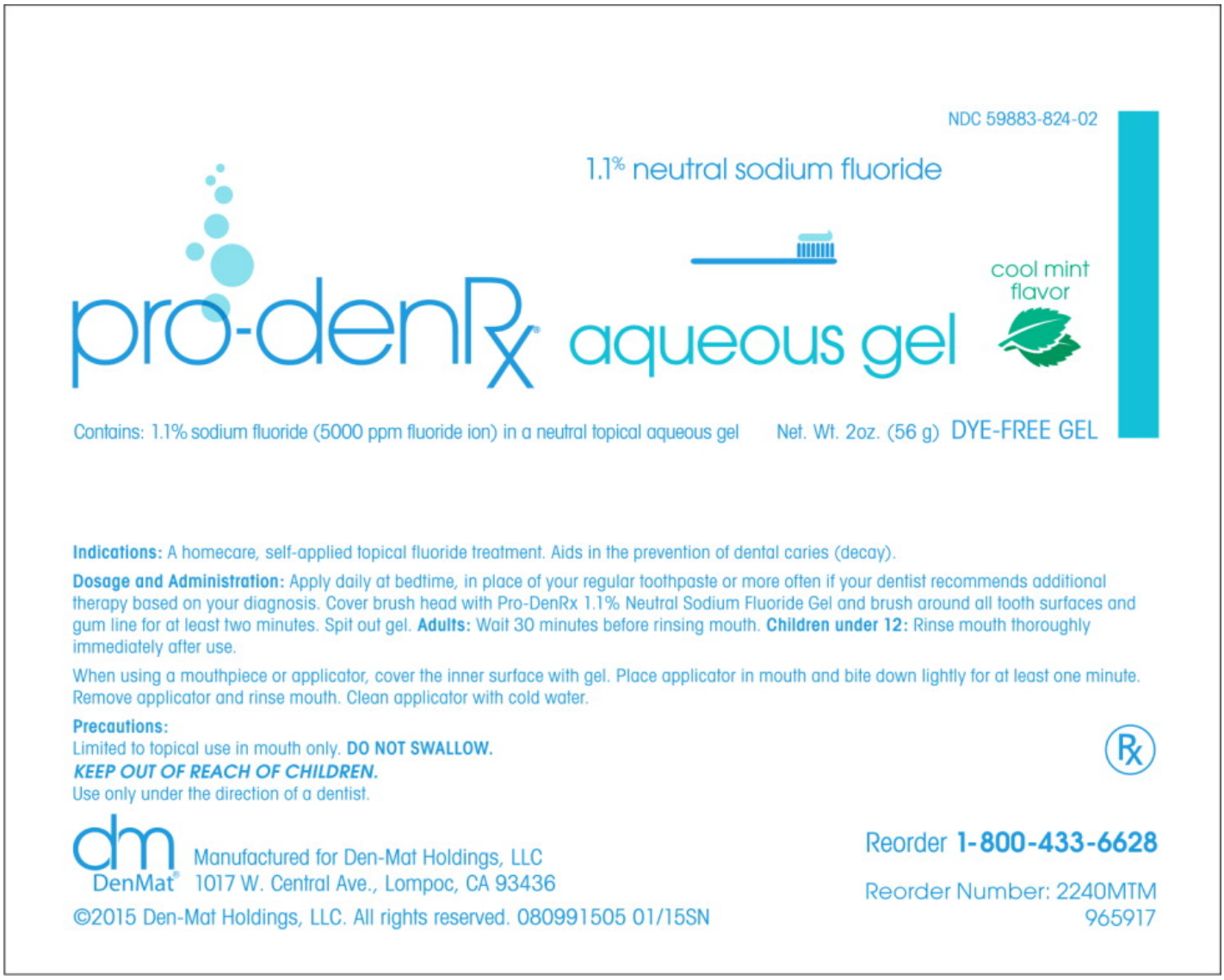
1.1% neutral sodium fluoride

pro-denRx ® aqueous gel

cool mint
flavor

Contains: 1.1% sodium fluoride (5000 ppm fluoride ion) in a neutral topical aqueous gel

Net Wt. 2oz. (56 g) DYE-FREE GEL



PRO-DEN RX

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59883-824
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	4.3 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:59883-824-02	1 in 1 CARTON	01/20/2009	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/20/2009	

Labeler - Den-mat Holdings, Llc (809857704)

Revised: 2/2019 Den-mat Holdings, Llc