PRO-DEN RX- sodium fluoride gel
DEN-MAT HOLDINGS, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pro-Den Rx

Drug Facts

OTC - ACTIVE INGREDIENT

Description:

A home care, self-applied topical fluoride treatment containing 1.1% Neutral

Sodium Fluoride (5000 ppm F) for daily use to aid in the protection against dental caries in adults and pediatric patients.

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

Inactive Ingredients:

Diatomite, Flavor, Glycerin, Carboxymethyl Cellulose, Phosphoric Acid,

Sodium Benzoate, Sodium Saccharin and Purified Water.

OTC - PURPOSE

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:

It is well recognized that regular use of 1.1% Neutral Sodium Fluoride (5000 ppm F) in mouthpiece applicators is safe and effective in preventing caries. [1-4] ProDenRx Brush-On Gel may be applied using a toothbrush. Plaque contributes to caries; therefore, reduction of plaque can help in preventing caries.

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

Warnings: PLEASE 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 (approx. 2 mg of fluoride) is not harmful.

Dosage and Administration:

Adults and Children over 6 years of age: Use in place of your regular toothpaste. Apply at bedtime or more often if your dentist recommends additional therapy based on the diagnosis. Cover brush head with ProDenRx 1.1% Neutral Sodium Fluoride Gel and brush around all tooth surfaces and gum line for at least 1 minute. Spit out gel. **Adults:** Wait 30 minutes before rinsing mouth.

For children under age 12: Rinse mouth thoroughly immediately after use.

Store at Room Temperature

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

Cherry Limeade: NDC 59883-821-02

References:

1. Accepted Dental Therapeutics Ed. 40 ADA Chicago, p. 405-407, 1984.

2. Englander HR, et al.: JADA 83:354-358 1971.

3. Englander HR, et al.: JADA 78:783-787 1969.

4. Englander HR, et al.: JADA 75:638-644 1967.

Rx Only

1-800-228-5595

REORDER NUMBER: 2250CLM

Made for and Distributed in US by: Zila Therapeutics, Inc.

P.O. Box 3889, Batesville, AR 72503

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

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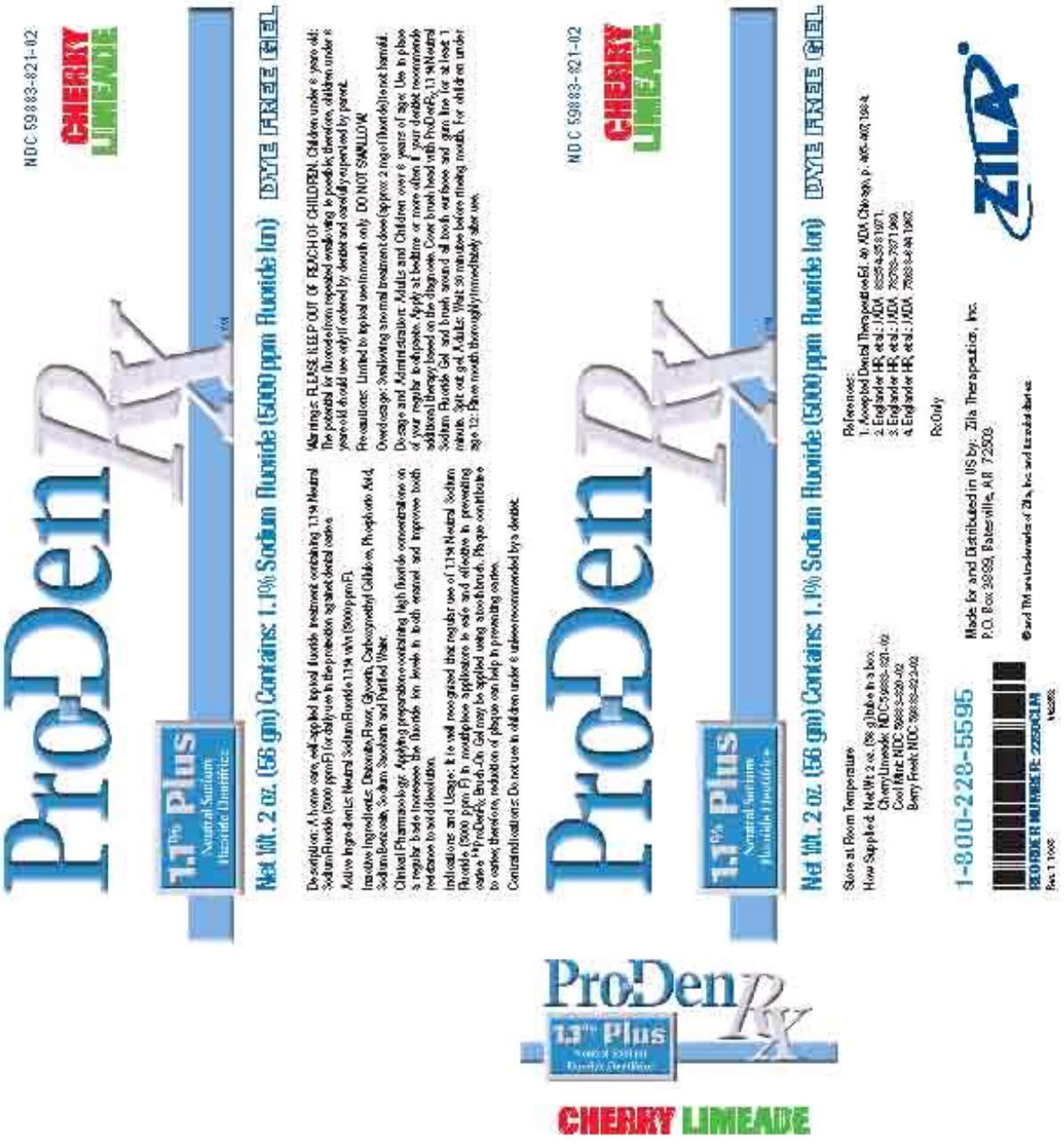
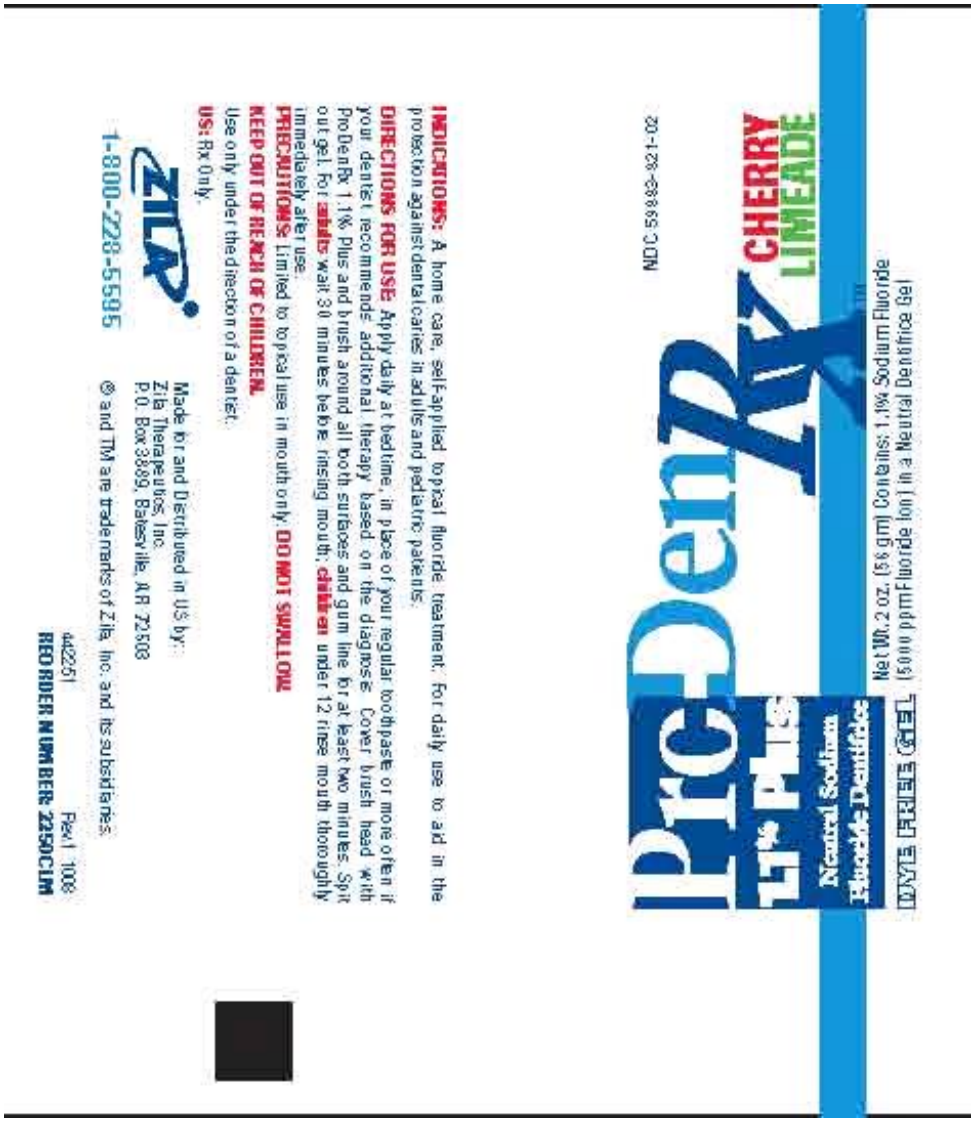
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





PRO-DEN RX

sodium fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59883-821
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	

PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-821-02	1 in 1 CARTON	11/21/2008	
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
OTC monograph final	part355	11/21/2008	

Labeler - DEN-MAT HOLDINGS, LLC (809857704)

Revised: 3/2019 DEN-MAT HOLDINGS, LLC