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

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.

OTC - ACTIVE INGREDIENT

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

INACTIVE INGREDIENT

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.

OTC - KEEP OUT OF REACH OF CHILDREN

PLEASE KEEP OUT OF REACH OF CHILDREN.

WARNINGS

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.

Berry Fresh: NDC 59883-822-02

Cherry Limeade: NDC 59883-821-02

Cool Mint: NDC 59883-820-02

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: 2250RBM

Made for and Distributed in US by: Zila Therapeutics, Inc.
P.O. Box 3889, Batesville, AR 72503

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PRO-DEN RX

sodium fluoride gel

Product Information	
Product Type	HUMAN OTC DRUG
Route of Administration	ORAL

Item Code (Source)
NDC:59883-820

ProDen RX™

NDC 59883-820-02

COOL MINT

1.1% Plus Neutral Sodium Fluoride Dentifrice

Net Wt. 2 oz. (56 gm) Contains: 1.1% Sodium Fluoride (5000 ppm Fluoride Ion) DYE FREE GEL

Description: A home care, self-applied topical fluoride treatment containing 1.1% Neutral Sodium Fluoride (5000 ppm F) for daily use in the protection against dental caries.

Active Ingredients: 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.

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.

ProDen RX 1.1% Plus Neutral Sodium Fluoride Dentifrice COOL MINT

ProDen RX™

NDC 59883-820-02

COOL MINT

1.1% Plus Neutral Sodium Fluoride Dentifrice

Net Wt. 2 oz. (56 gm) Contains: 1.1% Sodium Fluoride (5000 ppm Fluoride Ion) DYE FREE GEL

Store at Room Temperature

How Supplied: Net Wt. 2 oz. (56 g) tube in a box.
Cherry Limeade: NDC 59883-821-02
Cool Mint: NDC 59883-820-02
Berry Fresh: NDC 59883-822-02

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: 2250MTM

Rev. 1 1008 442248

Made for and Distributed in US by: Zila Therapeutics, Inc.
P.O. Box 3889, Batesville, AR 72503

ZILA®

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	MINT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59883-820-02	1 in 1 CARTON	10/31/2008	
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	10/31/2008	

Labeler - DEN-MAT HOLDINGS, LLC (809857704)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(59883-820)

Revised: 2/2019 DEN-MAT HOLDINGS, LLC