

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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INDICATIONS & USAGE SECTION

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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.

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

1.1% Plus
Natural Sodium
Fluoride (5000 ppm F)

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

ProDenRx

CHERRY LINEADE

NDC 59883-821-02

1.1% Plus
Natural Sodium
Fluoride (5000 ppm F)

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

ProDenRx

CHERRY LINEADE

NDC 59883-821-02

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Fluoride (5000 ppm F)

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ProDenRx

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NDC 59883-821-02

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Natural Sodium
Fluoride (5000 ppm F)

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ProDenRx

CHERRY LINEADE

NDC 59883-821-02

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

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

Inertive Ingredients: Deionized Water, Glycols, Carboxymethyl Cellulose, Phosphoric Acid, Sodium Bicarbonate, Sodium Saccharin and Purified Water.

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

Indications and Usage: It is well recognized that regular use of 1.1% Neutral Sodium Fluoride (5000 ppm F) in multiple applications is safe and effective in preventing caries. ProDenRx Brush-On Gel may be applied using toothbrush, finger or applicator to cavity preparations, reduction of plaque can help in preventing caries.

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

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

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Store at Room Temperature

How Supplied: Net Wt. 2 oz. (56 g) tube in a box.
Cherry Lineade: 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. 465-467, 1984.
2. Englander HR, ed.: ADA, 2005, 253-1071.
3. Englander HR, ed.: ADA, 2005, 257-1069.
4. Englander HR, ed.: ADA, 2003, 244-1067.

Rx Only

1-800-228-5595

800 228 5595

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ZILA

Rev. 1/10/08



NDC 59883-821-02

INDICATIONS: A home care, self-applied topical fluoride treatment. For daily use to aid in the protection against dental caries in adults and pediatric patients.

DIRECTIONS FOR USE: Apply daily at bedtime, in place of your regular toothpaste or more often if your dentist recommends additional therapy based on the diagnosis. Cover brush head with ProDenRX 1.1% Plus and brush around all tooth surfaces and gum line for at least two minutes. Spit out gel. For **adults** wait 30 minutes before rinsing mouth; **children** under 12 rinse mouth thoroughly immediately after use.

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

KEEP OUT OF REACH OF CHILDREN.

Use only under the direction of a dentist.

US: Rx Only.



1-800-228-5595

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P.O. Box 3899, Bakersville, AR 72508

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REG ORDER NUMBER 2250CUM

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