

NEUTRAGARD GEL MINT- topical neutral fluoride gel gel
Pascal Company, Inc.

NeutraGard Gel Mint

Dosage

RX Only in USA

Before dispensing remove cap and peel off seal

Contains: 1.1% w/w Sodium fluoride (provides 5000ppm fluoride)

Usual treatment does contains 1-3 mg fluoride. A 2.0oz tube contains 300 mg of fluoride

Indications & Usage

Indications and Usage

Aids in the prevention of dental cavities. This is an anti-cavity (preventive treatment gel, not a toothpaste. Read directions carefully before using. Clinical studies have shown that 1.1% sodium fluoride is safe and effective as an anti-cavity agent when used topically. This product should be applied with a toothbrush after brushing with a dentifrice toothpaste. It can be used in areas where drinking water is fluoridated since topical fluorides do not produce fluorosis when used as directed.

Adults and children 6 years of age and older: Use once daily after brushing with a dentifrice toothpaste. Apply a thin ribbon of gel to toothbrush and brush teeth thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow gel. For best effectiveness, do not eat or drink for 30 minutes after brushing. Supervise children less than 12 years of age as necessary when using this product to minimize swallowing.

Children under 6 years of age - consult a dentist or physician.

Contraindications

Hypersensitivity to fluoride

Warnings & Precautions

Do not swallow.

Keep this and all drugs out of reach of children.

For use only under supervision of a dental professional or physician.

Adverse Reactions: Developing teeth of children under 6 years of age may become permanently discolored if excess quantities are repeatedly swallowed. Reactions of individuals with fluoride hypersensitivity may include: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

Overdose: If you accidentally swallow more than used for brushing, administer calcium (e.g. milk) and seek professional medical assistance or contact local Poison Control Center immediately.

For product SDS information, please see company website at pascaldental.com or contact Pascal directly.

NeutraGard Gel is free of gluten, milk, soy, egg, peanut and tree nut products.

Store product between 59-86°F (15-30°C)



NeutraGard™ GEL

1.1% Neutral
Sodium Fluoride

pH 7™ 5000

Preventive
Treatment Gel
for Home Use

Mint

Only (In U.S.A.)

Before dispensing remove cap and peel off Seal

2 fl oz (60ml)

1.1% (w/w) Sodium Fluoride (provides 5000 ppm fluoride).

Use: Aids in the prevention of dental caries. This is an anti-cavity preventive treatment gel, not a toothpaste. Read directions carefully before using. Clinical studies have shown that 1.1% sodium fluoride is effective as an anti-cavity agent when used topically. This product should be applied with a toothbrush after brushing with a dentifrice toothpaste. It can be used in areas where drinking water is fluoridated. Seal fluorides do not protect fluorosis when used as directed.

Gel treatment dose contains 1 - 3 mg fluoride. A 2.0 oz tube contains 300 mg fluoride.

Use: Adults and children 6 years of age and older: Use once a day after brushing with a dentifrice toothpaste. Apply a thin ribbon of gel to toothbrush and brush teeth thoroughly. Allow the gel to remain on your teeth for 30 minutes. Do not eat or drink for 30 minutes after brushing. Supervise children less than 12 years of age as necessary when using this product to minimize risk of fluorosis.

Children under 6 years of age - consult a dentist or physician.

Warnings: Hypersensitivity to fluoride.

Precautions: DO NOT SWALLOW. Keep this and all drugs out of reach of children. For use only under supervision of a dental professional or physician.

Directions: Developing teeth of children under 6 years of age may become permanently discolored if excess quantities are repeatedly swallowed. Reactions of individuals with fluoride hypersensitivity may include: allergic dermatitis, urticaria, gastric distress, nausea, vomiting, and weakness.

Caution: If you accidentally swallow more than used for brushing, administer calcium (e.g. milk) and seek professional medical assistance or contact local Poison Control Center immediately.

For more information please see company website at www.pascalinternational.com or contact Pascal directly.

NeutraGard Gel is free of gluten, milk, soy, egg, peanut, and tree nut products.



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pH7 5000

Preventive Treatment Gel for Home Use

Mint Flavor

REF 11-715

NEUTRAGARD GEL MINT				
topical neutral fluoride gel gel				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10866-0110	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	11.28 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)		942 mg in 1 g		
Product Characteristics				
Color	green	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10866-0110-1	60 g in 1 TUBE; Type 0: Not a Combination Product	07/01/1999	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Export only		07/01/1999		

Labeler - Pascal Company, Inc. (009260217)

Establishment

Name	Address	ID/FEI	Business Operations
Pascal Company, Inc.		009260217	manufacture(10866-0110)

Revised: 1/2019

Pascal Company, Inc.