

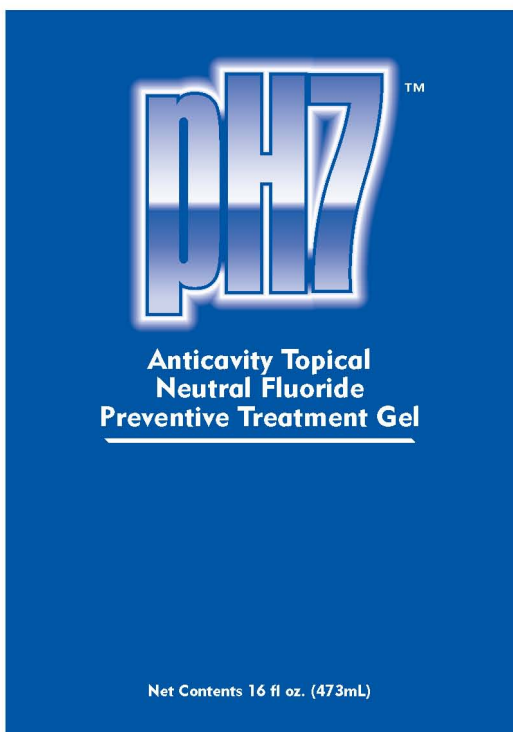
**PH7 GEL MINT- topical neutral fluoride gel gel**  
**Pascal Company, Inc.**

*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.*

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pH7 Anticavity Topical Neutral Fluoride Preventive Treatment Gel  
Mint

TOP SHOULDER OF BOTTLE

PASCAL pH7 GEL\_0412



**Contains:** Active Ingredient: Sodium fluoride 2.0% w/w (0.9% fluoride ion)

**Indications:** Professionally applied dental caries preventive.

**Contraindications:** Contraindicated in individuals who are hypersensitive to fluoride.

**Warnings:** Keep out of reach of children. For topical intraoral use only. For professionally applied, in-office fluoride treatment only.

**Precautions:**

- Not for systemic treatment. Do not swallow.
- Do not use on patients with an allergy to fluoride.
- pH7 Gel contains artificial flavor and color; confirm that no known patient allergies exist.
- Special care should be used when administering to children under 6 years of age so that gel is not swallowed.
- Contact with abraded or sensitive oral tissue may produce discomfort.
- If more than is ordinarily used for treatment is swallowed, administer calcium (milk) and contact your local Poison Control Center immediately.

**Dosage and directions for Use:**

Usual dosage is approximately 2.75 – 9.0 grams of pH7 Gel per dual arch treatment (depending on tray size).

1. After prophylaxis remove excess fluid from teeth.
2. Fill applicator tray 1/3 full with gel.
3. Insert filled tray into patient's mouth and instruct to bite down gently for one minute, or up to four minutes.
4. After treatment time is completed remove tray and have patient expectorate residual gel.
5. For maximum benefits for the prevention of caries, instruct patient not to rinse, eat, or drink for 30 minutes.

Repeat treatment at least once or twice a year. For patients with rampant or active caries, repeat treatment once or twice every six months.

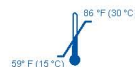
If contents have become frozen, warm to room temperature and shake well before using.

For product MSDS information please see company website at [pascaldental.com](http://pascaldental.com) or contact Pascal directly.

Pascal's pH7 Gel is free of gluten, soy, milk, egg, peanut and tree nut products.

Rx Only (in USA) For professional use only.

 **Pascal** International, Inc. 2929 NE Northrup Way  
Bellevue, WA USA 98004  
425.827.4694 • 800-426-8051  
[www.pascaldental.com](http://www.pascaldental.com) Made in USA SN62250/0412



BOTTOM OF BOTTLE  
100LPI

REFLEX BLUE C

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### Other Safety Information

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<b>PH7 GEL MINT</b>				
topical neutral fluoride gel gel				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:10866-0093	
<b>Route of Administration</b>	TOPICAL, BUCCAL, DENTAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
Sodium Fluoride (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU408O)		fluoride ion	9.05 mg in 1 g	
<b>Product Characteristics</b>				
<b>Color</b>	green	<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	MINT	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10866-0093-1	473 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/1993	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
unapproved drug other		05/01/1993		

**Labeler** - Pascal Company, Inc. (009260217)

**Establishment**

Name	Address	ID/FEI	Business Operations
Pascal Company, Inc.		009260217	manufacture(10866-0093)

Revised: 3/2015

Pascal Company, Inc.