60 SECOND TASTE CHOCOLATE VANILLA- topical apf fluoride gel gel Pas cal 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.

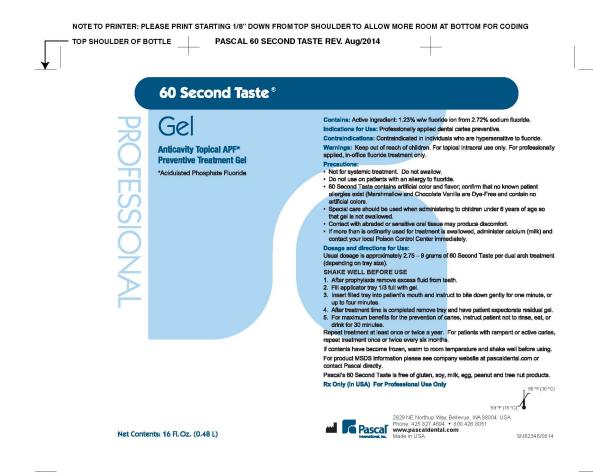
60 Second Taste Gel

Anticavity Topical APF*

Preventive Treatment Gel

*Acidulated Phosphate Fluoride

Chocoloate Vanilla



PMS 302 C

PMS 544 C

BLACK



Contains:

Active Ingredient: 1.23% w/w fluoride ion from 2.72% sodium fluoride

Contraindications

Contraindicated in individuals who are hypersensitive to fluoride

Warnings and Precautions

Keep out of reach of children. For topical intraoral use only. For professionally applied in office fluoride treatment only.

Not for systemic treatement. Do no swallow.

Do not use on patients with an allergy to fluoride.

60 Second Taste contains artifical color and flavor; confirm that no known patient allergies exist. Marshmallow and Chocolate Vanilla are dye free and contain no artificial colors.

Special care should be used when administering to children under 6 years of age so that gel is not swallowed.

Contact with abraided or sensitive oral tissue may produce discomfort.

If more than is ordinarily used for treatment is swallowed, administer calcium such as milk and contact your local Poison Control Center immediately.

Dosage and Directions for Use:

Usual dosage is approximately 2.75-9.0 grams of 60 Second Taste per dual arch treatment depending on tray size.

Shake well before use.

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.

Other Safey Information

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

Pascal's 60 Second Taste is free gluten, soy, milk, egg, peanut and tree nut products.

Rx only in USA. For Professional Use only.

60 SECOND TASTE CHOCOLATE VANILLA

topical apf fluoride gel gel

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10866-0885	
Route of Administration	TOPICAL, DENTAL, BUCCAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium fluoride (UNII: 8ZYQ1474W7) (Fluoride ion - UNII:Q80VPU408O)	Fluoride ion	27.73 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
Saccharin Sodium (UNII: SB8ZUX40TY)	5.5 mg in 1 g

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	CHOCOLATE	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10866-0885-	480 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	0.1/15/2007	

2	Product	01/13/200/		
N/ - 1 - 4' T - C	/*			
Marketing Information				
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		01/15/2007		

Labeler - Pascal Company, Inc. (009260217)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pascal Company, Inc.		009260217	manufacture(10866-0885)	

Revised: 3/2015 Pascal Company, Inc.