

60 SECOND TASTE ORANGE TWIST- topical apf 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.

60 Second Taste Orange Twist

Contains:

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

Contraindicated in individuals who are hypersensitive to fluoride.

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

Not for system treatment. Do not swallow.

Do not use on patients with an allergy to fluoride.

60 Second Taste contains artificial 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 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 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.

NOTE TO PRINTER: PLEASE PRINT STARTING 1/8" DOWN FROM TOP SHOULDER TO ALLOW MORE ROOM AT BOTTOM FOR CODING

TOP SHOULDER OF BOTTLE

PASCAL 60 SECOND TASTE REV. Aug/2014

60 Second Taste®

PROFESSIONAL

Gel

**Anticavity Topical APF*
Preventive Treatment Gel**

*Acidulated Phosphate Fluoride

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

Indications for Use: 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.
- 60 Second Taste contains artificial 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 abraded or sensitive oral tissue may produce discomfort.
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For product MSDS information please see company website at pascidental.com or contact Pascal directly.

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

Rx Only (in USA) For Professional Use Only

Net Contents: 16 Fl.Oz. (0.48 L)



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www.pascidental.com
Made in USA

SN62346/0814

PMS 302 C PMS 544 C BLACK

Orange Twist

REF 10-022

SN72624/0410



60 Second Taste Gel
Anticavity Topical APF*

Preventive Treatment Gel

*Acidulated Phosphate Fluoride

Orange Twist

60 SECOND TASTE ORANGE TWIST

topical apf fluoride gel gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10866-0485
Route of Administration	BUCCAL, DENTAL, TOPICAL		

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

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10866-0485-2	480 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/1993	

Labeler - Pascal Company, Inc. (009260217)

Establishment

Name	Address	ID/FEI	Business Operations
Pascal Company, Inc.		009260217	manufacture(10866-0485)

Revised: 5/2015

Pascal Company, Inc.