60 SECOND TASTE STRAWBERRY- 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.

Contains:

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

Contraindications:

Contraindicated in individuals who are hypersensitive to fluoride.

Warnings & Precautions

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 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 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 Safety Information

For product MSDS information please see company website at pascaldental.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.

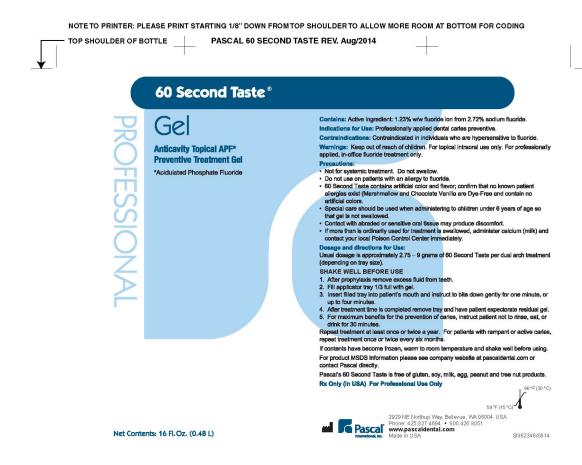
60 Second Taste Gel

Anticavity Topical APF*

Preventive Treatment Gel

*Acidulated Phosphate Fluoride

Strawberry



PMS 302 C PMS 544 C BLACK



60 SECOND TASTE STRAWBERRY

topical apf fluoride gel gel

Product Information

Product TypeHUMAN PRESCRIPTION DRUGItem Code (Source)NDC:10866-0685Route of AdministrationDENTAL, BUCCAL, TOPICAL

Active Ingredient/Active Moiety

| , | | |
|---|--------------------------|-----------------|
| Ingredient Name | Basis of Strength | Strength |
| Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU4080) | Fluoride Ion | 27.73 mg in 1 g |

Product Characteristics

| Color | pink | Score | |
|----------|------------|--------------|--|
| Shape | | Size | |
| Flavor | STRAWBERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|----------------------|---|-------------------------|-----------------------|
| 1 | NDC:10866- 0685-2 | 480 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/01/1988 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 04/01/1988 | |
| | | 04/01/1988 | |

Labeler - Pascal Company, Inc. (009260217)

| Establishment | | | | |
|----------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Pascal Company, Inc. | | 009260217 | manufacture(10866-0685) | |

Revised: 9/2022 Pascal Company, Inc.