

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

NeutraGard Gel Strawberry

Dose:

Contains:

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

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

Indications & Directions:

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.

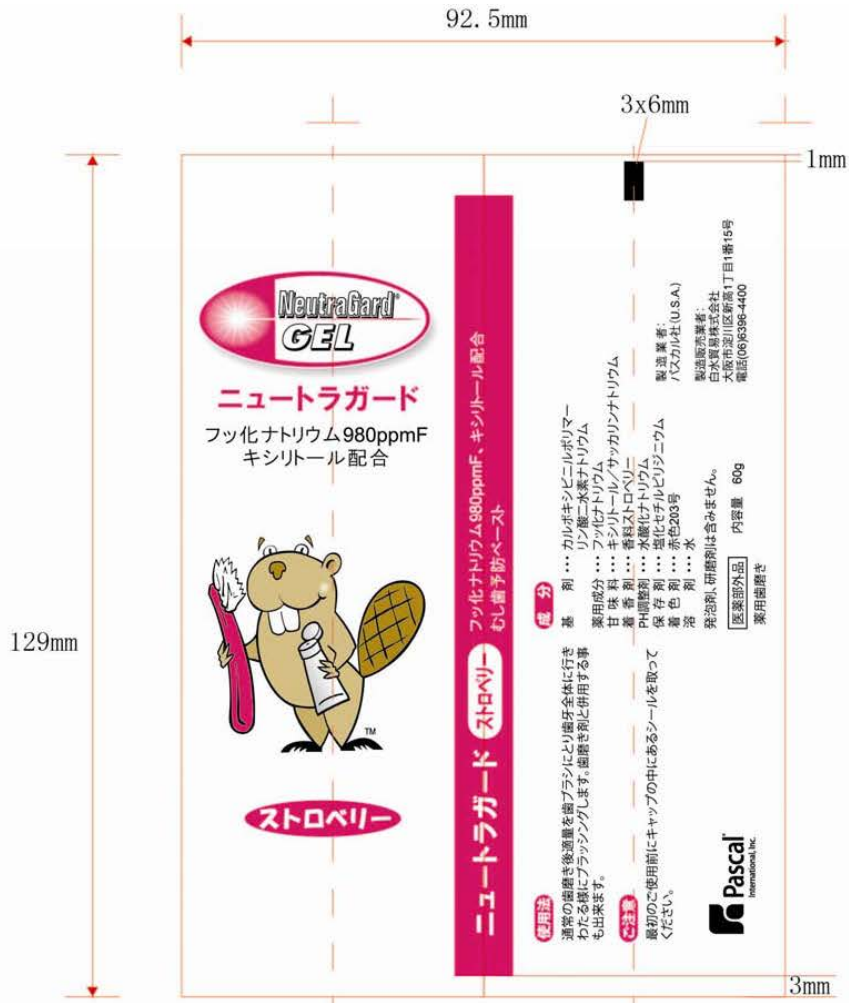
Overdose: If you accidentally swallow more than used for brushing, administer calcium (e.g. milk) and seek professional medical assistance or contact local Poison Control Center immediately.

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



- k
- 213c
- 1255c
- die line, does not print
边框, 不印刷

088816 树脂印 (Offset printing) : 213c 1255c k

| | |
|------------------------------------|---|
| 产品编号 Product Ref. # | 088816 |
| 制作/修改人 Processed By | Qiaoxin |
| 制作/修改日期 Date | 2010/09/26 |
| 打样单/定单号 Sample/Purchase Order # | |
| 不上光高度 Unvarnished area | |
| 附加说明 Remarks | |
| 确认签字 Approved By | Nydia White Digitally signed by Nydia White DN: CN = Nydia White, C = US, O = Pascal International, OU = Quality Assurance Date: 2010.09.29 06:40:53 -0700 |
| 日期 Date | |

pH7 5000

Preventive Treatment Gel for Home Use

Tropical Blast Flavor

REF 11-718

Before dispensing remove cap and peel off seal

NEUTRAGARD GEL STRAWBERRY

topical neutral fluoride gel gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:10866-0117 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 7 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------------|
| EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF) | 1 mg in 1 g |
| CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) | 0.1 mg in 1 g |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | 2.5 mg in 1 g |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | 18.5 mg in 1 g |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10866-0117-1 | 56.7 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(10866-0117) |

Revised: 1/2019

Pascal Company, Inc.