# GERIGENTLE-GOOD MORNING- sodium floride paste, dentifrice Geri-Gentle Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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## **Gerigentle-Good morning New**

## **Drug Facts**

## **Active ingredient**

Sodium Fluoride 0.22% w/w

## **Purpose**

**Anticavity Toothpaste** 

#### Use

aids in the prevention of dental cavities

## Warnings

Keep out of the reach of children under 6 years of age!

• If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately

#### **Directions**

- Do not Swallow
- Supervise children as necessary until capable of using without supervision
- Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing)
- Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
- Children under 6 years of age: Do not use unless directed by a dentist or physician

#### Other Information

- Store at 59°-86°F (15°-30°C)
- Avoid excessive heat

## **Inactive Ingredients**

Flavor, Glycerin, PEG-1500, Silica, Sodium Benzoate, Sodium Carboxymethyl Cellulose, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Tetra Sodium Pyrophosphate, Titanium Dioxide, Water

## PRINCIPAL DISPLAY PANEL - 43 g Tube Carton



## **GERIGENTLE-GOOD MORNING**

sodium floride paste, dentifrice

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:69771-091 |
| Route of Administration | DENTAL         |                    |               |

| Active Ingredient/Active Moiety                                     |                          |                 |  |
|---|--------------------------|-----------------|--|
| Ingredient Name   | <b>Basis of Strength</b> | Strength        |  |
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | FLUORIDE ION             | 0.22 g in 100 g |  |

| Inactive Ingredients                        |          |
|---|----------|
| Ingredient Name                             | Strength |
| GLYCERIN (UNII: PDC6A3C0OX)                 |          |
| POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A) |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         |          |
| WATER (UNII: 059QF0KO0R)                    |          |
| SORBITOL (UNII: 506T60A25R)                 |          |

| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                                 |  |
|--|--|
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                           |  |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311) |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                                |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                                 |  |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z)                            |  |

| P | Packaging            |   |                         |                       |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code            | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:69771-091-<br>38 | 43 g in 1 TUBE; Type 0: Not a Combination Product | 01/15/2015              |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph final   | part355                                     | 01/15/2015              |                       |
|                       |   |                         |                       |

## Labeler - Geri-Gentle Corporation (080367686)

Revised: 12/2022 Geri-Gentle Corporation