**PRIMO APF- sodium fluoride gel**
**Tri State Dental**

*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.*

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**Active Ingredient:**

Fluoride Ion 1.23%

Available from 2.09% Sodium Fluoride and Hydrofluoric Acid

**Purpose:**

Fluoride Treatment Gel

**Indications and Usage:**

- A stable thixotropic fluoride treatment gel used to help prevent dental decay.
- For Professional Use Only. This product is not intended for home or unsupervised use.

**Warnings:**

- Keep out of reach of children.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.
- Read directions carefully before using.

**Dosage and Administration:**

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

1. After thorough prophylaxsis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.

2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).

3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

**Other Information:**

Store at controlled room temperature 59° to 86°F (15°-30°C).

Protect from freezing.

**Inactive Ingredients:**

Citric Acid, FD&C Red #40, FD&C Yellow #5 (tartrazine) as a color additive, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.


## PRIMO APF

sodium fluoride gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:69509-058 |

| Route of Administration | DENTAL |
|---|---|

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **SODIUM FLUORIDE** (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 5.6 g in 454 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **MAGNESIUM ALUMINUM SILICATE** (UNII: 6M3P64V0NC) | |
| **PHOSPHORIC ACID** (UNII: E4GA8884NN) | |
| **POLYSORBATE 20** (UNII: 7T1F30V5YH) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |
| **XYLITOL** (UNII: VCQ006KQ1E) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | ORANGE, VANILLA | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:69509-058-15 | 454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/2013 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 09/01/2013 | |

## Labeler - Tri State Dental (176048478)