## 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).

#### Inactive Ingredients:

Citric Acid, FD&C Blue #1, FD&C Red #3, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.

<pre>     Primo     APF GEL </pre>	Active Ingredient:       Purpose:         Fluoride Ion 1.23%       Fluoride Treatment Gel         Available from 2.09% Sodium Fluoride and Hydrofluoric       Acid.         Indications and Usage:       • A stable thixotropic fluoride treatment gel used to help         prevent dental decay.       • For Professional Office Use Only. This product is not intended for home or unsupervised consumer use.		
Acidulated Phosphate Fluoride Treatment Gel <i>with Xylitol</i> 1.23% Fluoride Ion	<ul> <li>Warnings: <ul> <li>Keep out of reach of children.</li> <li>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.</li> <li>Read directions carefully before using.</li> </ul> </li> <li>Dosage and Administration: <ul> <li>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.</li> <li>After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.</li> <li>Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).</li> <li>Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.</li> </ul> </li> </ul>		
GRAPE Re-order #: FGGR	Other Information: • Store at controlled room temperature 59° to 86°F (15°-30°C). Protect from freezing. Inactive Ingredients: Citric Acid, FD&C Blue #1, FD&C Red #3, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.		
GLUTEN FREE	Manufactured for: Manufactured for: 845 Third Avenue 6th Floor New York, NY 10022 800-232-6874		
Ronly Net wt. 16 oz (454 g)	www.primodentalproducts.com MADE IN THE USA 99092485 Rev 9/13		
<b>PRIMO APF</b> sodium fluoride gel			

#### **Product Information**

**Product Type** 

HUMAN PRESCRIPTION DRUG

Item Code (Source)

Route of Administration	DEN
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NDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       09         Marketing Information       1000000000000000000000000000000000000		
Ingredient Name         Ingredient Name <th><b>Basis of Strength</b></th> <th>Strength</th>	<b>Basis of Strength</b>	Strength
Ingredient Name  ITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)  MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64VONC)  PHOSPHORIC ACID (UNII: E4GA8884NN)  POLYSORBATE 20 (UNII: 7T1F30V5YH)  GODIUM BENZOATE (UNII: 0)245FE5EU)  GACCHARIN SODIUM (UNII: B88Z UX40TY)  WATER (UNII: 059QF0KO0R)  KANTHAN GUM (UNII: TTV12P4NEE)  YULITOL (UNII: 059QF0KO0R)  GANTHAN GUM (UNII: TTV12P4NEE)  YULITOL (UNII: VCQ006KQ1E)  FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C RED NO. 3 (UNII: PN2ZH5LOQY)  TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  Product Characteristics  Color purple Size  Flavor GRAPE Imprint Code  Package Description Imprint Code  Package Description 0 G  Marketing Information	) FLUORIDE ION	5.6 g in 454 g
Ingredient Name  ITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)  MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64VONC)  PHOSPHORIC ACID (UNII: E4GA8884NN)  POLYSORBATE 20 (UNII: 7T1F30V5YH)  GODIUM BENZOATE (UNII: 0)245FE5EU)  GACCHARIN SODIUM (UNII: B88Z UX40TY)  WATER (UNII: 059QF0KO0R)  KANTHAN GUM (UNII: TTV12P4NEE)  YULITOL (UNII: 059QF0KO0R)  GANTHAN GUM (UNII: TTV12P4NEE)  YULITOL (UNII: VCQ006KQ1E)  FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C RED NO. 3 (UNII: PN2ZH5LOQY)  TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  Product Characteristics  Color purple Size  Flavor GRAPE Imprint Code  Package Description Imprint Code  Package Description 0 G  Marketing Information		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) PHOSPHORIC ACID (UNII: E4GA8884NN) POLYSORBATE 20 (UNII: 071F30V5YH) GOUYSORBATE 20 (UNII: 0)245FE5EU) GACCHARIN SODIUM (UNII: 0)245FE5EU) GACCHARIN SODIUM (UNII: S88ZUX40TY) WATER (UNII: 059QF0K00R) KANTHAN GUM (UNII: TTV12P4NEE) KANTHAN GUM (UNII: TTV12P4NEE) KANTHAN GUM (UNII: TTV12P4NEE) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 3 (UNII: PN2ZH5LOQY) FTTANIUM DIOXIDE (UNII: 15FIX9V2JP) POCULCT Characteristics Color purple Score Shape Size Flavor GRAPE Imprint Code Contains GRAPE Imprint Code Contains Of Acid gin 1 BOTTLE, PLASTIC; Type 0: Not a MARKETING Information MARKETING Information		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)         PHOSPHORIC ACID (UNII: 7T1F30V5YH)         SODIUM BENZOATE (UNII: 0)245FE5EU)         SACCHARIN SODIUM (UNII: SB8ZUX40TY)         WATER (UNII: 059QF0K00R)         KANTHAN GUM (UNII: TTV12P4NEE)         KYLITOL (UNII: VCQ006KQ1E)         SD&C BLUE NO. 1 (UNII: H3R47K3TBD)         SD&C RED NO. 3 (UNII: PN2ZH5LOQY)         STACK RED NO. 3 (UNII: 15FIX9V2JP)         Product Characteristics         Contains       Score         Shape       GRAPE         Flavor       GRAPE         Contains       Yaff g in 1 BOTTLE, PLASTIC; Type 0: Not a         Marketing Information       Oc		Strength
PHOSPHORIC ACID (UNII: E4GA8884NN) POLYSORBATE 20 (UNII: 7T1F30V5YH) GODIUM BENZOATE (UNII: 0)245FE5EU) GACCHARIN SODIUM (UNII: SB8ZUX40TY) WATER (UNII: 059QF0K00R) KANTHAN GUM (UNII: T1712P4NEE) (YLITOL (UNII: VCQ006KQ1E) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 3 (UNII: PN2ZH5LOQY) TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  Product Characteristics Color purple Score Shape 5 GRAPE Imprint Code Contains 5 GRAPE Imprint Code Contains 6 GRAPE 1 Marketing Information		
PolysorBATE 20 (UNII: 711F30V5YH) GODUM BENZOATE (UNII: 0)245FE5EU) GACCHARIN SODIUM (UNII: SB8ZUX40TY) WATER (UNII: 059QF0K00R) CANTHAN GUM (UNII: TTV12P4NEE) CYLITOL (UNII: VCQ006KQ1E) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 3 (UNII: PN2ZH5L0QY) FITANIUM DIOXIDE (UNII: 15FIX9V2JP) Product Characteristics Color purple Score Shape Size Flavor GRAPE Imprint Code Contains Size Package Description Imprint Code Package Description 0 Marketing Information Marketing Information		
Golum BENZOATE (UNII: 0/245FE5EU)   SACCHARIN SODIUM (UNII: SB8ZUX40TY)   WATER (UNII: 059QF0K00R)   KANTHAN GUM (UNII: TTV12P4NEE)   CYLITOL (UNII: VCQ006KQ1E)   ED&C BLUE NO. 1 (UNII: H3R47K3TBD)   ED&C RED NO. 3 (UNII: PN2ZH5LOQY)   TTANIUM DIOXIDE (UNII: 15FIX9V2JP)   Product Characteristics   Color   purple   Score   Size   Imprint Code   Color   Packaging   ***********************************		
AACCHARIN SODIUM (UNII: SB8ZUX40TY) WATER (UNII: 059QF0KO0R) CANTHAN GUM (UNII: TTV12P4NEE) CYLITOL (UNII: VCQ006KQ1E) CD&C BLUE NO. 1 (UNII: H3R47K3TBD) CD&C RED NO. 3 (UNII: PN2ZH5LOQY) TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  Product Characteristics Color purple Score Color QRAPE Imprint Code Contains GRAPE Imprint Code Contains  Packaging  Marketing Information		
WATER (UNII: 059QF0K00R)         KANTHAN GUM (UNII: TTV12P4NEE)         CYLITOL (UNII: VCQ006KQ1E)         SD&C BLUE NO. 1 (UNII: H3R47K3TBD)         SD&C RED NO. 3 (UNII: PN2Z H5LOQY)         TITANIUM DIOXIDE (UNII: 15F1X9V2JP)         Product Characteristics         Color       purple         Score         Shape       GRAPE         Flavor       GRAPE         Contains       Imprint Code         Packaging       V         #       Item Code         Package Description       I         NDC:69509-       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product         Marketing Information       oc		
KANTHAN GUM (UNII: TTV12P4NEE)         KYLITOL (UNII: VCQ006KQ1E)         CD&C BLUE NO. 1 (UNII: H3R47K3TBD)         CD&C RED NO. 3 (UNII: PN2ZH5LOQY)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color       purple         Size         Siape       GRAPE         Imprint Code         Contains       Imprint Code         Package Description       I         NDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       05		
Cylitol (UNII: VCQ006KQ1E)         Color       1 (UNII: 15FIX9V2JP)         Color       purple       Score         Shape       Size         Flavor       GRAPE       Imprint Code         Contains       Package Description       I         NDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       05		
Back Blue No. 1 (UNII: H3R47K3TBD)   Back RED No. 3 (UNII: PN2ZH5LOQY)   RITANIUM DIOXIDE (UNII: 15FIX9V2JP)   Product Characteristics   Color purple   Score   Solar   Solar  <		
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)   FTTANIUM DIOXIDE (UNII: 15FIX9V2JP)   Product Characteristics   Color purple   Score   Shape Size   Flavor GRAPE   Contains Imprint Code   Package Description   NDC:69509- 454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product   Marketing Information		
FITTANIUM DIOXIDE (UNII: 15FIX9V2JP)   Product Characteristics   Color purple   Score   Size   Bape   GRAPE   Imprint Code   Contains   Package Description   Item Code   Package Description   NDC:69509-   055-15   A NDC:69509- 055-15 Combination Product Of Marketing Information		
Product Characteristics Color purple Score Shape GRAPE Imprint Code Contains GRAPE Imprint Code Package Description I NDC:69509- 454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 0 of Combination Product		
Color purple Score Size Size Size Imprint Code Contains Flawor GRAPE Imprint Code Mprint Code Package Description MDC:69509- 055-15 02 454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 0 05		
Shape Size Size Imprint Code GRAPE Imprint Code Imprint Code Size Size Size Size Size Size Size Siz		
Flavor       GRAPE       Imprint Code         Contains       Packaging       Imprint Code         Packaging       Item Code       Package Description       Imprint Code         MDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       09		
Contains         Packaging         # Item Code       Package Description       I         MDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       05		
Packaging         #       Item Code       Package Description       I         NDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       09         Marketing Information       Information       Information		
#       Item Code       Package Description       Item Code         NDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       05		
#       Item Code       Package Description       Item Code         NDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       05		
NDC:69509- 055-15       454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       09         Marketing Information       1000000000000000000000000000000000000		
055-15     Combination Product       Marketing Information	Aarketing Start Ma Date	rketing End Date
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Marketing Application Number or Monograph M Category Citation	arketing Start Ma Date	rketing End Date
napproved drug 09/0	01/2013	

# Labeler - Tri State Dental (176048478)