# NRG APF- sodium fluoride gel IQ Dental Supply, LLC

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: | Purpose: |
|--------------------|----------|
|--------------------|----------|

Fluoride Ion 1.23%......Flouride 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 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, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.

NRG

#### Distributed by IQ Dental

# APF Gel Thixotropic with Xylitol

Acidulated
Phosphate Fluoride
Treatment Gel
1.23% Fluoride Ion

**GLUTEN FREE** 

## Cherry

Re-order#: NRGAPFG-CH

Ronly

IMPORTANT: READ DIRECTIONS FOR PROPER USE

MADE IN USA Net Wt. 16 oz (454 g)

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99090581 Rev 08/2013

### **NRG APF**

sodium fluoride gel

#### **Product Information**

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:42756-1111

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             | 5.6 g in 454 g |

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

| Product Characteristics |        |              |  |
|-------------------------|--------|--------------|--|
| Color                   | red    | Score        |  |
| Shape                   |        | Size         |  |
| Flavor                  | CHERRY | Imprint Code |  |
| Contains                |        |              |  |

| l | Packaging |                      |   |                         |                       |
|---|-----------|----------------------|---|-------------------------|-----------------------|
|   | #         | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |
|   | 1         | NDC:42756-<br>1111-7 | 454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2013              |                       |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| unapproved drug other |   | 08/01/2013              |                       |  |
|                       |   |                         |                       |  |

## Labeler - IQ Dental Supply, LLC (800349763)

Revised: 1/2022 IQ Dental Supply, LLC