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.

| 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, 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.

NRG

Distributed by IQ Dental

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99090587 Rev 08/2013

APF Gel Thixotropic with Xylitol

Acidulated
Phosphate Fluoride
Treatment Gel
1.23% Fluoride Ion

GLUTEN FREE

Mango Smoothie

Re-order#: NRGAPFG-MS

Ronly

IMPORTANT: READ DIRECTIONS FOR PROPER USE

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

NRG APF

sodium fluoride gel

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:42756-1115

Route of Administration DENTAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | FLUORIDE ION | 5.6 g in 454 g |

| Ingredient Name | Strength |
|--|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| 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 | orange | Score |
| Shape | | Size |
| Flavor | MANGO (MANGO SMOOTHIE) | Imprint Code |
| Contains | | |

| l | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | | NDC:42756- 1115-7 | 454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2013 | |

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

Labeler - IQ Dental Supply, LLC (800349763)

Revised: 1/2022 IQ Dental Supply, LLC