

## **IRIS 60 SECOND APF- sodium fluoride gel**

### **Benco 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 Ingredients:**

1.23% Fluoride Ion

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 Office Use Only. This product is not intended for home or unsupervised consumer 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 of four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment twice a year.
  - After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
  - Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
  - Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

#### **Other information:**

Do not store above 25°C/77°F. Do not freeze.

#### **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

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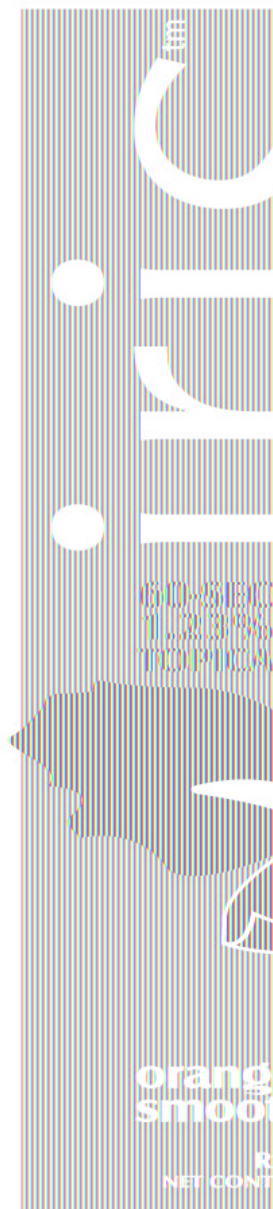
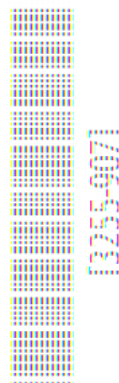
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<b>IRIS 60 SECOND APF</b>			
sodium fluoride gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:66975-053
<b>Route of Administration</b>	DENTAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	5.6 g in 454 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE (Orange Smoothie)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66975-053-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/14/2012	

**Labeler** - Benco Dental (015108087)

Revised: 2/2022

Benco Dental