

**GELATO APF- sodium fluoride gel**  
**Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.**

*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% .....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.

**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 twice a year.

1. After thorough prophylaxis, 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:**

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

**Inactive ingredients:**

Citric Acid, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20,

Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol. May contain blue #1, green #3, red #3, red #40, yellow #5 (tartrazine), yellow #6 as a color additive.

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with Xylitol  
Acidulated Phosphate Fluoride  
Treatment Gel  
GLUTEN FREE  
Rx only

1.23%  
Fluoride Ion

FOR PROFESSIONAL USE ONLY  
IMPORTANT: READ DIRECTIONS FOR PROPER USE

MANUFACTURED BY:  
**keystone**  
INDUSTRIES

480 S. Democrat Rd.  
Gibbstown, NJ 08027  
www.keystoneind.com  
1-800-333-3131

MADE IN USA

99087151 Rev 06/2016

Net Wt. 16 oz. (454g)

<p>Bubble Gum</p> <p>24-08677</p> <p>Re-order#: 24-08677</p> <p>99087107</p>	<p>Cherry</p> <p>24-08277</p> <p>Re-order#: 24-08277</p> <p>99087108</p>	<p>Cotton Candy</p> <p>24-10177</p> <p>Re-order#: 24-10177</p> <p>99087109</p>	<p>Grape</p> <p>24-01877</p> <p>Re-order#: 24-01877</p> <p>99087110</p>	<p>Mango Smoothie</p> <p>24-10677</p> <p>Re-order#: 24-10677</p> <p>99087111</p>	<p>Marshmallow</p> <p>24-09977</p> <p>Re-order#: 24-09977</p> <p>99087117</p>
<p>Mint</p> <p>24-00577</p> <p>Re-order#: 24-00577</p> <p>99087118</p>	<p>Mint Dye Free</p> <p>24-04477</p> <p>Re-order#: 24-04477</p> <p>99087119</p>	<p>Orange Vanilla</p> <p>24-11077</p> <p>Re-order#: 24-11077</p> <p>99087120</p>	<p>Piña Colada</p> <p>24-08777</p> <p>Re-order#: 24-08777</p> <p>99087121</p>	<p>Strawberry</p> <p>24-03377</p> <p>Re-order#: 24-03377</p> <p>99087122</p>	<p>Vanilla Dye Free</p> <p>24-01977</p> <p>Re-order#: 24-01977</p> <p>99087123</p>

## GELATO APF

sodium fluoride gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68400-121
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<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: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

**Product Characteristics**

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MARSHMALLOW	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-121-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2016	

**Marketing Information**

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

(014769301)

## Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	manufacture(68400-121) , label(68400-121)

Revised: 1/2022

Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.