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.

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, Xantham Gum, Xylitol. May contain blue #1, green #3, red #3, red #40, yellow #5 (tartrazine), yellow #6 as a color additive.



sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	ltem Code (Source)	NDC:68400-110
Route of Administration	DENTAL		

Ingredient Name Basis of Strength Strength SODIUM FLUORIDE (UNII: 82YQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 5.6 g in 454 Inactive Ingredients Ingredient Name Strength Inactive Ingredients Ingredient Name Strength Inactive Ingredients Strength Strength Ingredient Allows Strength Strength Sodium Aluminum Silicate Strength Strength Sodium Benzoart (UNII: Stagastan) Strength Strength Sodium Benzoart (UNII: Stagastan) Strength Strength Sodium Sobium (UNII: Trigovsth) Strength Strength Stactalin Solution (UNII: Stagastan) Stren								
Sobilum FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 5.6 g in 454 Inactive Ingredients Strength Strength CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) MAGMESIUM ALUMINUM SILICATE (UNII: 2968PHW8QP) MAGMESIUM ALUMINUM SILICATE (UNII: 2968PHW8QP) MAGMESIUM ALUMINUM SILICATE (UNII: 2968PHW8QP) Sobilum BENZOATE (UNII: 71130V5YH) SODIUM BENZOATE (UNII: 0)245FESEU) SACCHARIN SODIUM (UNII: 515K39V2JP) WATER (UNII: 059QF0KOOR) XANTHAN GUM (UNII: TTV12P4NEE) XYLITOL (UNII: VC2006KQ1E) FDAC REE NO. 3 (UNII: P122HSLOQY) FDAC REE NO. 3 (UNII: P172HI93AB) Product Characteristics Color purple Score Size Flavor GRAPE Imprint Code Oatte Contains <th co<="" th=""><th colspan="7">Active Ingredient/Active Moiety</th></th>	<th colspan="7">Active Ingredient/Active Moiety</th>	Active Ingredient/Active Moiety						
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Magnesium Aluminum silicate (UNII: 6M3P64V0NC) Image: Second			Ingredient Nam	ie		Strength		
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FD&C YELLOW NO. 5 (UNII: 1753WB2F1M) FD&C YELLOW NO. 6 (UNII: H77VEI93A8) FD&C YELLOW NO. 6 (UNII: H77VEI93A8) FD Color purple Score Shape gRAPE Imprint Code Flavor GRAPE Imprint Code Contains Score State Prockaging Marketing Start Marketing Encode 1 NDC:68400- 454 g in 1 BOTTLE, PLASTIC; Type 0: Not a 06/01/2016	FD&C RED NO. 3	(UNII: PN2ZH5LC	QY)					
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Marketing Information

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unapproved drug other	12/14/2012	

(014769301)			
Establishment			
Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	manufacture(68400-110) , label(68400-110)
Registorie maastries			

Revised: 1/2022 Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.