

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, 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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MANUFACTURED BY:
keystone
INDUSTRIES
480 S. Democrat Rd.
Gibbstown, NJ 08027
www.keystoneind.com
1-800-333-3131
MADE IN USA

FOR PROFESSIONAL USE ONLY
IMPORTANT: READ DIRECTIONS FOR PROPER USE

1.23%
Fluoride Ion

Net Wt. 16 oz. (454g)

99087151 Rev 06/2016

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

GELATO APF

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68400-111
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

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-111-15	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(68400-111) , label(68400-111)

Revised: 1/2022

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