

GELATO NEUTRAL PH- 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:

Sodium Fluoride 2%

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 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 four minutes.
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, Potassium Hydroxide, 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.

Gelato
Neutral PH Gel

with Xylitol
 For In-office Topical Oral Application
 GLUTEN FREE
 Rx only

FOR PROFESSIONAL USE ONLY
 IMPORTANT: READ DIRECTIONS FOR PROPER USE

2% Neutral Sodium Fluoride

Net Wt. 16 oz. (454g)

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 Sodium Fluoride 2% Fluoride Treatment Gel

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MANUFACTURED BY:
keystone Industries
 480 S. Democrat Road
 Gibbstown, NJ 08027 USA
 keystoneindustries.com
 1-800-333-3131
MADE IN USA

99087652 Rev 04/2018

Neutral
Bubble Gum

24-01777
 Re-order#: 24-01777
 99087601

Neutral
Mint Dye Free

24-00777
 Re-order#: 24-00777
 99087604

Neutral
Mint

24-00477
 Re-order#: 24-00477
 99087605

Neutral
Strawberry

24-01677
 Re-order#: 24-01677
 99087606

GELATO NEUTRAL PH

sodium fluoride gel

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:68400-324

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	4.086 g in 454 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-324-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/01/2013	

Labeler - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc
(014769301)

Establishment

Name	Address	ID/FEI	Business Operations
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc		014769301	manufacture(68400-324) , label(68400-324)

Revised: 4/2024

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