

**GELATO PERIO MAINTENANCE RINSE- stannous fluoride concentrate
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:

Stannous Fluoride 0.63% Concentrate (0.12% w/v fluoride ion).

Purpose:

Anticavity, antigingivitis, antihypersensitivity mouthrinse

Indications and Usage:

Aids in the prevention of dental decay. Helps prevent gingivitis. Helps control plaque bacteria. Increases protection against painful tooth sensitivity. This product must be used under the supervision of a dentist.

Warnings:

- Keep out of reach of children.
- Do not swallow. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- Do not use until diluted.
- This product may produce surface staining of the teeth.
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Directions:

Adults and children 6 years of age and older:

- Do not use before mixing with water. Use immediately after preparing the rinse.
- Shake concentrate well before mixing with water.
- Remove cap and replace with pump.
- Rotate spout counter clockwise to extend.
- Depress pump until rinse comes to the tip of the pump.
- Depress pump twice into cup provided (1/8oz). Add water to line (1oz) on cup. Mix well.
- Vigorously swish rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing.
- Instruct children under 12 years of age in the use of this product (to minimize

swallowing). Supervise children as necessary until capable of using without supervision.

Children under 6 years of age: Consult a dentist or doctor.

Inactive Ingredients:

Flavor, Glycerin, Methyl Paraben, Propyl Paraben and Sodium Saccharin.

Other Information:

Store at controlled room temperature 59° - 86°F (15°-30°C). Protect from freezing.

0.63% Stannous Fluoride
Concentrated Solution

Perio
Maintenance
Rinse



Perio
Maintenance
Rinse
Alcohol Free

0.63% Stannous Fluoride
Concentrated Solution
Rx only

Important: Read directions for proper use.

Net Wt. 10 oz (283.5g)

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Perio
Maintenance
Rinse
Alcohol Free

0.63% Stannous Fluoride
Concentrated Solution
Rx only

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Net Wt. 10 oz (283.5g)

Perio
Maintenance
Rinse
Alcohol Free

Raspberry
#24-10377

Mint
#24-11877

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

MADE IN USA
9906800 Rev 01/17

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MADE IN USA 99088751 Rev:4/16

Gelato
Perio Maintenance Rinse
Alcohol Free

0.63% Stannous Fluoride Concentrated Solution
Rx only

MANUFACTURED BY: **keystone industries**
480 S. Democrat Rd.
Gibbstown, NJ 08027
www.keystoneind.com
1-800-333-3131

Important: Read directions for proper use.

Net Wt. 10 oz. (283.5g)

Raspberry



24-10377

Re-order#: 24-10377
99088706

Mint



24-11877

Re-order#: 24-11877
99088703

GELATO PERIO MAINTENANCE RINSE

stannous fluoride concentrate

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68400-202
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.34 g in 283.5 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	white (heavy liquid)	Score	
Shape		Size	

Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-202-10	283.5 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/2013	

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

Registrant - 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(68400-202) , label(68400-202)

Revised: 4/2024

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