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:

Anticavitiy, 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.
- This product may produce surface staining of the teeth. Adequate tooth-brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

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.

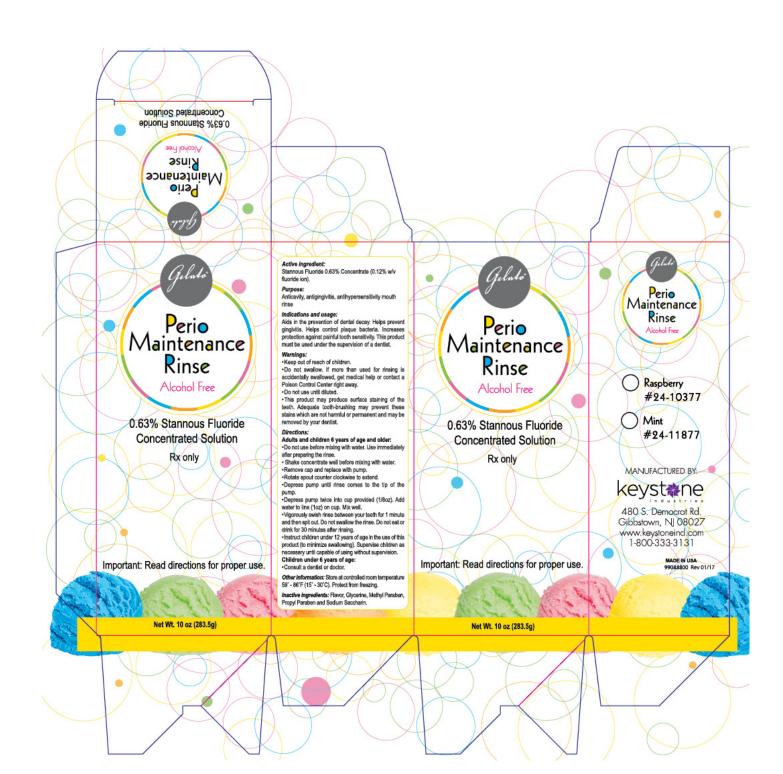
Children under 6 years of age: Consult a dentist or doctor.

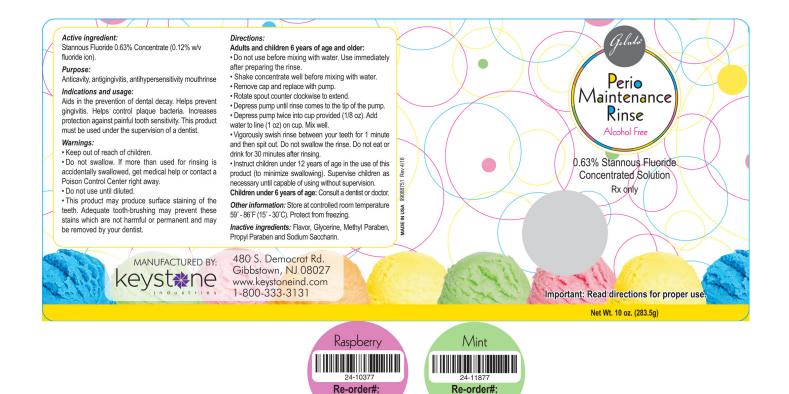
Inactive Ingredients:

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.





GELATO PERIO MAINTENANCE RINSE

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68400-206	
Route of Administration	DENTAL			

24-11877

99088703

24-10377

99088706

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					
mactive mgreatent	Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C	0OX)			_	
METHYLPARABEN (UNII: A2I8C7HI9T)					
PROPYLPARABEN (UNII: Z8IX2SC10H)					
SACCHARIN SODIUM (UNII: SB8ZUX40TY)					
Product Characteristics					
Color	white (heavy liquid)	Sc	ore		
Shape		Siz	ze		

Flavor		RAS	RASPBERRY Imprint Code			
Contains						
Packaging						
#	ltem Code		Package Description		Marketing Start Date	Marketing End Date
	NDC:68400- 206-10	283.5 g in 1 Combination	BOTTLE, PLASTIC; Type 0: Not Product	a	01/01/2017	
Marketing Information						
	Marketing Category	Appl	ication Number or Monog Citation	Iraph	Marketing Start Date	Marketing End Date
una oth	approved drug er			C	02/01/2013	
oth	er					

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(68400-206) , label(68400-206)	

Revised: 4/2024 Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.