

GELATO HOMECARE- stannous fluoride gel
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Stannous Fluoride 0.4%

Purpose

Fluoride preventive treatment gel

Uses

- Home Care is a stable fluoride gel for home use.
- Aids in the prevention of dental decay.

Warning

- Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.
- This is a fluoride preventive treatment gel, not a toothpaste. Read directions carefully before using.

Directions

Adults and children 6 years of age and older: Twist off cap to remove foil seal. Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing. 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.

Other Information

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

Inactive Ingredients

Carbopol, Flavor, Glycerine, Malic Acid, Sodium Carboxymethylcellulose, Water, Xanthan Gum.

Questions or comments?

1-800-333-3131 or www.keystoneind.com

Home-Care
0.4% Stannous Fluoride Gel

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Red Berry
#24-10577

Mint
#24-10477

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

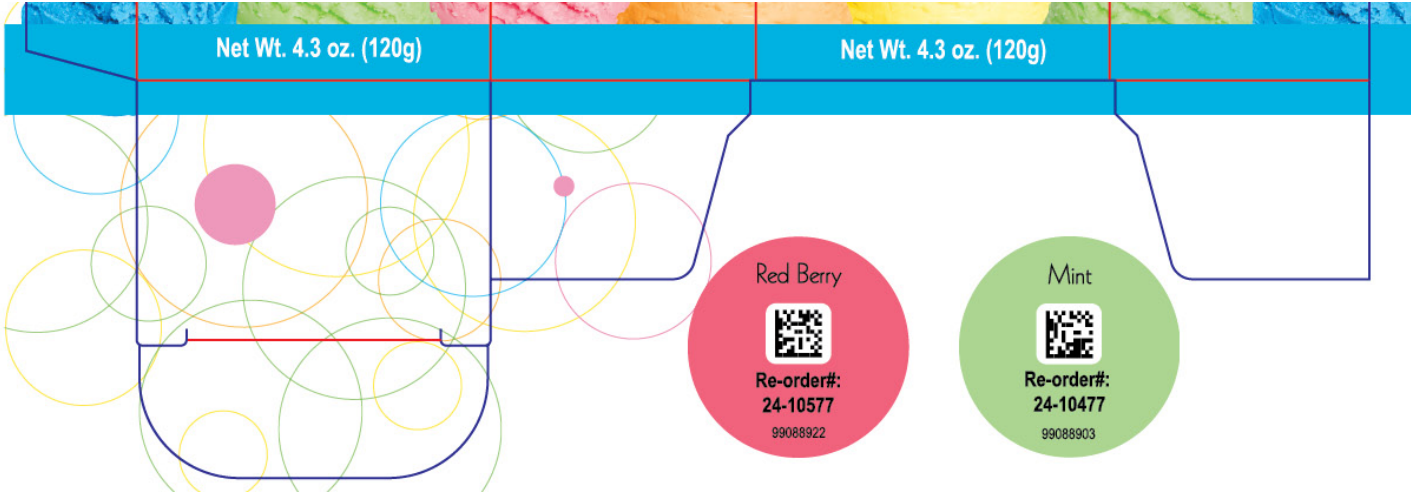
99088999 Rev 09/2016

IMPORTANT: READ DIRECTIONS ON PROPER USE

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Net Wt. 4.3 oz. (120g)

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Red Berry



Re-order#:
24-10577
99088922

Mint



Re-order#:
24-10477
99088903

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Stannous Fluoride 0.4%	Fluoride preventative treatment gel

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99099050 Rev 4/14



Net Wt. 4.3 oz. (120g)

GELATO HOMECARE

stannous fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68400-201
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.116 g in 120 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
MALIC ACID (UNII: 817L1N4CKP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white (Cloudy)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-201-04	120 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/05/2013	

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(68400-201) , label(68400-201)

Revised: 1/2022

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