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

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.

Warnings:

- 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

www.keystoneind.com

Drug Facts

Active Ingredient:

Purpose:

Stannous Fluoride 0.4%Fluoride preventative treatment gel

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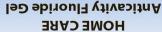
Questions or comments? 1-800-333-3131 www.keystoneind.com

Manufactured in the USA by:



480 S. Democrat Road Gibbstown, NJ 08027 US/ 99098106 REV 03/2017











HOME CARE

FLUORIDE PREVENTIVI REATMENT GEL

0.4% STANNOUS FLUORIDE



IMPORTANT: READ DIRECTIONS FOR PROPER USE.

PEPPERMINT



Net Weight: 4.3 oz. (120g)

SORBET **HOME CARE Anticavity Fluoride Gel**

Drug Facts

Active Ingredients: Purpose: Stannous Fluoride 0.4% ... Fluoride Preventative Treatment Gel

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

Warnings:

 Keep out of the reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

The 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 preventative treatment gel not a toothpaste. Read directions carefully before using.

Directions:

Adults and children 6 years of age and older: Adults and children 6 years of age and older:
Twist off cap and 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 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 projecting regulationis) 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

Inactive Ingredients: Carbopol, Flavor, Glycerin, Malic Acid, Sodium Carboxymethylcellulose, Water, Xanthan Gum.

Questions or comments? 1-800-333-3131 www.keystoneind.com

Manufactured by:



480 S. Democrat Road Gibbstown, NJ 08027 800-333-3131 www.keystoneind.com

99075154 REV 08/2013



HOME CARE

FLUORIDE PREVENTIV TREATMENT GEL

0.4% STANNOUS FLUORIDE



IMPORTANT: READ DIRECTIONS FOR PROPER USE.

PEPPERMINT



Re-order# 24-21077



Net Weight: 4.3 oz. (120g)



HOME CARE Anticavity Fluoride Gel

Made in USA

SORBET HOMECARE

stannous fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68400-800
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: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)			
MALIC ACID (UNII: 817L1N4CKP)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Product Characteristics			
Color	white (cloudy)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:68400-800- 04	120 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		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(68400-800) , label(68400-800)	

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