

GELATO 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.

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?

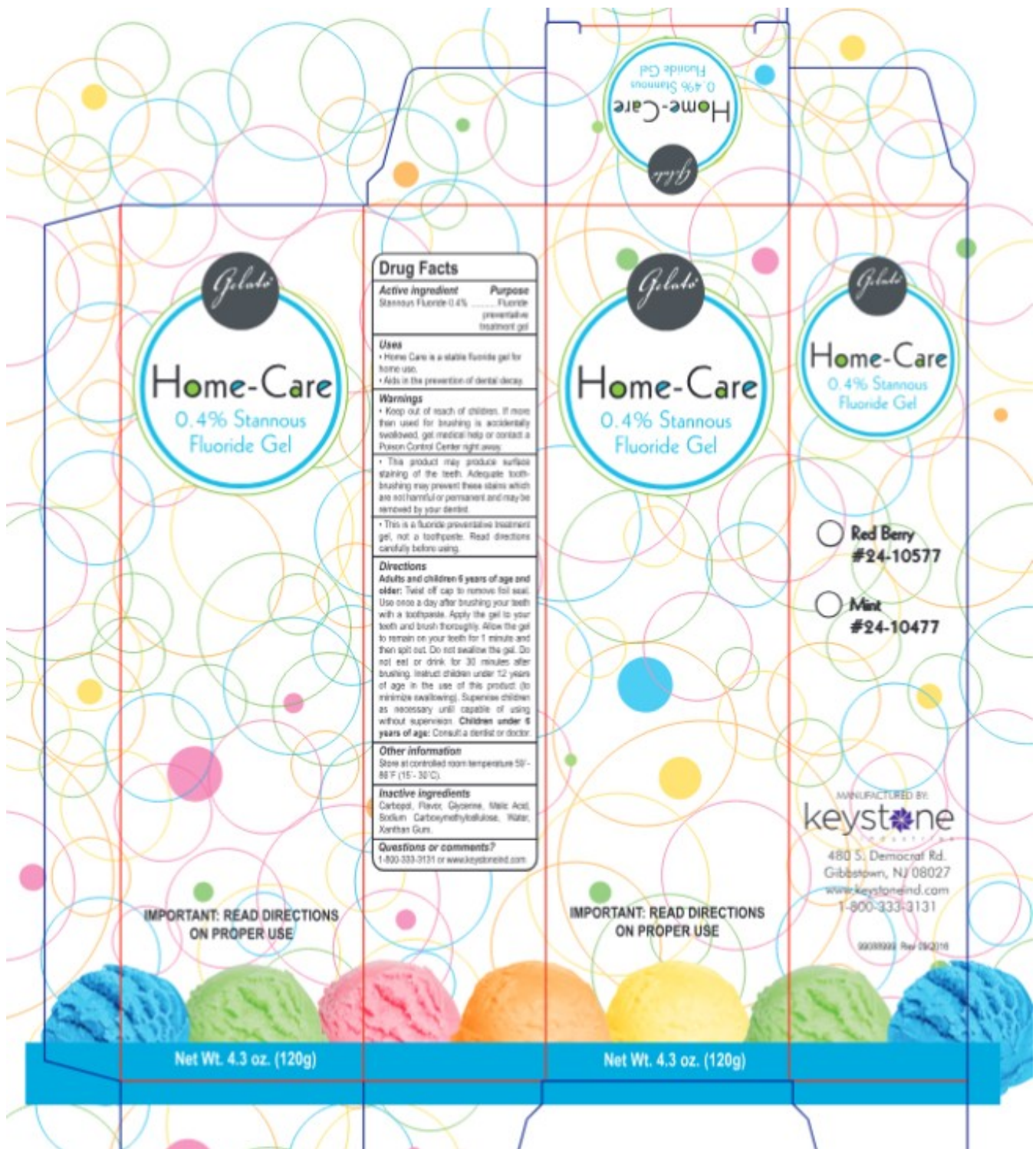
1-800-333-3131 or www.keystoneind.com



 PMS 306

 PMS 367

 PMS Cool Gray 11



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:Q80VPU4080)	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 Drug	M021	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)