GELATO NEUTRAL PH- sodium fluoride gel
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:

Sodium Fluoride 2%

Purpose:

Fluoride Treatment Gel

Indications and Usage:

- A stable thixotropic fluoride treatment gel used to help prevent dental decay.
- For Professional Office Use Only. This product is not intended for home or unsupervised consumer use.

Warnings:

- Keep out of reach of children.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.
- Read directions carefully before using.

Dosage and Administration:

Shake well before use. This is a four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment twice a year.

1. After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.

2. Instruct patient to bite down lightly but firmly for four minutes.

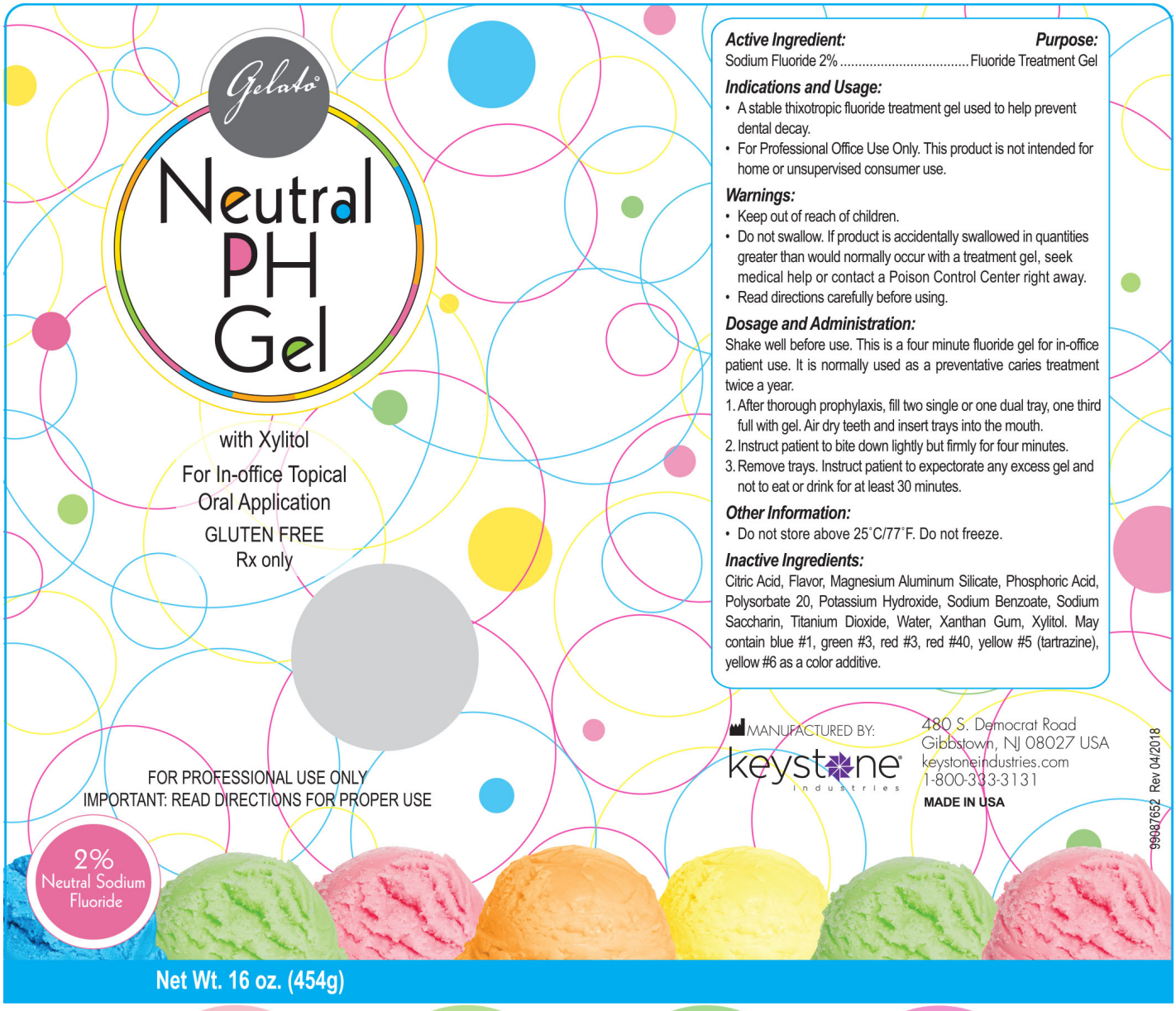
3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

Other Information:

• Do not store above 25°C/77°F. Do not freeze.

Inactive Ingredients:

Citric Acid, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Potassium Hydroxide, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol. May contain blue #1, green#3, red #3, red #40, yellow #5 (tartrazine), yellow #6 as a color additive.



GELATO NEUTRAL PH

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68400-115
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	4.086 g in 454 g

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	pink	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-115-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug		03/01/2013	

other		03/01/2013	

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(68400-115) , label(68400-115)

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