

GELATO NEUTRAL PH - sodium fluoride aerosol, foam
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.

This is a prescription fluoride treatment foam used to help prevent dental decay.

Do not swallow. Keep out of reach of children. Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container. Do not spray toward open flame. For professional use only.

Distilled water, Polaxamer, Triethanolamine, Phosphoric Acid, Sodium Saccharine, Sodium Laureth Sulfate, Hydrofluoric Acid, Xylitol, Potassium Hydroxide, Propellant A31.

- Store at controlled room temperature 59-86 F (15-30 C)
- Protect from freezing

NDC# 068400-138-04

Gelato

FOAM NEUTRAL PH

With Xylitol

2% Neutral Sodium Fluoride
For In-office Topical Application

GLUTEN FREE

Rx Only

Bubble Gum

4 minute treatment

NEUTRAL FOAM

Active Ingredient: 2% Sodium Fluoride
Purpose: Fluoride Treatment Gel.

Indications and Usage: This is a prescription fluoride treatment foam used to help prevent dental decay.

Warnings: Do not swallow. Keep out of reach of children. Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container. Do not spray toward open flame. For Professional Use Only.

Instructions for Use:

- Remove cap from can. Prior to each use, shake can thoroughly for at least 15 seconds.
- To dispense, invert the can completely upside down. Slowly depress nozzle to dispense foam into a fluoride tray (foam will expand slightly higher than fluoride tray).
- Air dry teeth thoroughly and insert tray(s) into patient's mouth. Instruct patient to bite down and leave the tray in contact with the teeth for 4 minutes.
- Use a saliva ejector during treatment to minimize ingestion of product.
- Remove tray(s) and have patient expectorate.
- Instruct patient not to eat, drink or rinse for 30 minutes after treatment.

Inactive Ingredients: Distilled Water, Poloxamer, Triethanolamine, Phosphoric Acid, Sodium Saccharine, Sodium Benzoate, Sodium Laureth Sulfate, Hydrofluoric Acid, Xylitol, Potassium Hydroxide, Propellant A31.

Other Information:

- Store at controlled room temperature 59°-86°F (15°-30° C)
- Protect from freezing

Shake well before each use

INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE

Manufactured by
DEEPAK PRODUCTS, LLC
A Division of Keystone Industries

Miami, FL 33186
1-877-8-DEEPAK

Re-order#: 24-25477

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MADE IN USA

4.4 oz (125g)

www.deepakproducts.com

GELATO NEUTRAL PH
sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68400-138
Route of Administration	DENTAL, TOPICAL, ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.5 g in 125 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-138-04	125 g in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/11/2011	

Labeler - Deepak Products, inc. (124886743)**Establishment**

Name	Address	ID/FEI	Business Operations
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Deepak Products, inc.		124886743	manufacture
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Revised: 8/2011

Deepak Products, inc.