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 on 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

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: 059QF0KO0R)	
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

Deepak Products, inc.		124886743	manufacture