

**GELO-X- sodium fluoride gel, dentifrice**  
**Dharma Research, Inc.**



# gelo-X

## Bubble Gum

APF THIXOTROPIC GEL  
with Xylitol & Vitamin E

Acidulated  
Phosphate Fluoride  
Treatment Gel  
1.23% Fluoride Ion

GLUTEN FREE

1 minute or 4 minute  
Treatment

17 fl. oz. (500ml)



MADE IN USA

**Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
Sodium Fluoride 2.09%.....	Anticaries

**Uses** Prescription fluoride treatment gel used to prevent dental decay.

**Warnings**

- Keep out of the 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.
- Do not use on patients with an allergy to fluoride.
- Ionite APF Gel contains artificial color, confirm that no known patient allergies exist.
- For professional use only.

**Directions**

- Shake well before use.
- This is a four minute or one minute fluoride gel for in-office patient use.
- For best results, use at least twice a year.
- After thorough prophylaxis, fill two single or one dual tray one third full with gel. Air dry teeth and insert trays into the mouth.
- Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
- Remove trays, instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

**Other information**

- Store at 59° – 86°F (15°-30° C).
- Protect from freezing.
- Ionite APF Gel is free of gluten, soy milk, egg, peanut and tree nut products.

**Inactive ingredients**

Citric Acid, FD&C Red No. 40 (C.I. 16035), Flavor, Hydrofluoric Acid, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Purified Water, Sodium Benzoate, Sodium Saccharin, Sweetness Enhancer, Titanium Dioxide, Tocopheryl Acetate, Xantham Gum, Xylitol.

Importer and License Holder:  
 Dentorient Fuss LTD 512834284  
 P.O.B 2232 Tel Aviv Israel  
 Tel 03-6393640 Fax 03-6393645  
 www.idental.co.il  
 Israeli Registration Number:  
 25360003 (medical device)

reorder code:  
**geloX001**  
 expiry date and batch  
 printed on the bottom

**GELO-X**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:53045-208
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	10.241 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-208-17	490 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
export only		01/01/2016	

**Labeler** - Dharma Research, Inc. (078444642)

**Registrant** - Dharma Research, Inc. (078444642)

## Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-208)