

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



# gelo-X

*Mint*



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 Green No. 3 (C.I. 42053), FD&C Yellow No. 5 (C.I. 19140), Flavor, Hydrofluoric Acid, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Purified Water, Sodium Benzoate, Sodium Saccharin, Sweetness Enhancer, Titanium Dioxide, Tocopheryl Acetate, Xanthan 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:  
g e l o x 0 0 3

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:53045-211
<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 GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>HYDROFLUORIC ACID</b> (UNII: RGL5YE86CZ)	
<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>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-211-17	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(53045-211)