

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



gelo-X

Orange

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

Active Ingredient	Purpose
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), 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:
geloX007
 expiry date and batch
 printed on the bottom

GELO-X

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-212
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-212-17	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(53045-212)