

IONITE APF- sodium fluoride gel
Dharma Research, 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](#).

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

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

- 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 Fluoride.
- Ionite APF Gel contains artificial color, confirm that no known patient allergies exist.
- For professional use only.

- 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

NDC# 53045-206-08

Strawberry Shortcake **ionite**

APF THIXOTROPIC GEL
with Xylitol & Vitamin E

Acidulated
Phosphate Fluoride
Treatment Gel
1.23% Fluoride Ion

GLUTEN FREE

1 minute or 4 minute
Treatment



8.5 fl. oz. (250 ml)

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 2.72%	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, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Purified Water, Sodium Benzoate, Sodium Saccharin, Sweetness Enhancer, Titanium Dioxide, Tocopheryl Acetate, Xanthan Gum, Xylitol.

Manufactured by:
 **DHARMA**
 RESEARCH, INC.
WWW.DHARMARESEARCH.COM
 5220 N.W. 72 Avenue
 Unit 15, Miami, FL 33166
 1-877-833-3725

Rev. B, Date: 05/14/2020
Re-order#: **56-00052**



MADE IN USA

NDC#53045-206-17

Strawberry Shortcake **ionite**

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)

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 2.72%	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.
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- Ionite APF Gel is free of gluten, soy milk, egg, peanut and tree nut products.

Inactive ingredients

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Rev. B, Date: 05/14/2020
Re-order#: **56-00007**
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MADE IN USA

IONITE APF

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-206
Route of Administration	DENTAL, ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	6.027 g in 490 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY (Strawberry Shortcake)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-206-17	490 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2013	
2	NDC:53045-206-08	245 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2013	

Labeler - Dharma Research, inc. (078444642)

Registrant - Dharma Research, inc. (078444642)

Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, inc.		078444642	manufacture(53045-206)