

**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](#).*

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- 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# 53045-201-08

Cherry Tart **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)

**MADE IN USA**

## 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:



[WWW.DHARMARESEARCH.COM](http://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#: **56-00051**



NDC#53045-201-17

Cherry Tart **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)

**MADE IN USA**

#### 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, Xantham Gum, Xylitol.

Manufactured by:  
**DHARMA**  
RESEARCH, INC.  
WWW.DHARMARESEARCH.COM  
5220 N.W. 72 Avenue  
Unit 15, Miami, FL 33198  
1-877-833-3725

Rev. B, Date: 05/14/2020  
Re-order#: **56-00002**  
  
3 53045 100014 17

NDC#53045-201-30

Cherry Tart **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



1 gallon (3.8L)

**MADE IN USA**

#### 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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#### Inactive ingredients

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5220 N.W. 72 Avenue  
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1-877-833-3725

Rev. B, Date: 05/14/2020  
Re-order#: **56-00060**  
  
3 53045 100025 3

**IONITE APF**  
sodium fluoride gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:53045-201
<b>Route of Administration</b>	DENTAL, ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	10.241 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

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-201-17	490 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2013	
2	NDC:53045-201-08	245 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2013	
3	NDC:53045-201-38	3724 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(53045-201)

Revised: 11/2020

Dharma Research, inc.