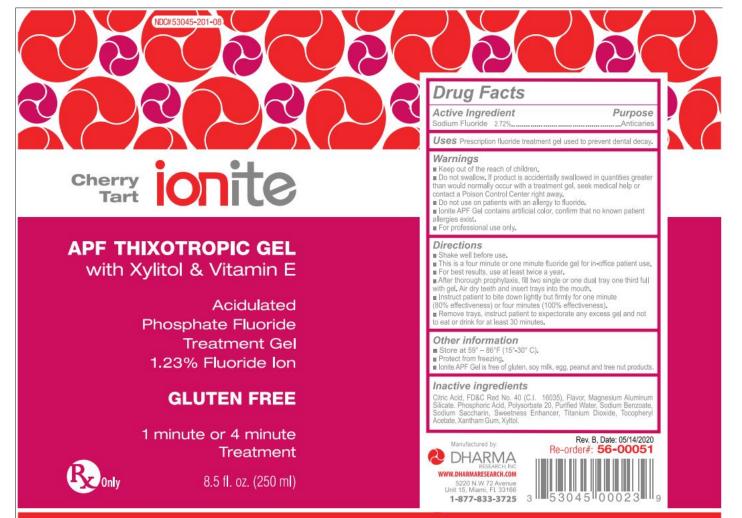
IONITE APF- sodium fluoride gel Dharma Research, inc.

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 kno.wn 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



MADE IN USA



IONITE APF

sodium fluoride gel

Product Information

Product Type		HUMAN PRESCRIPTION DR	UG	Ite m Cod	e (Source)	NDC:5304	5-201			
Route of Administra	tion	DENTAL, ORAL	L, ORAL							
Active Ingredien	t/Active M	niety								
Active Ingredient/Active Moiety Ingredient Name Basis of Strengtl						ath Sta	ength			
					-	in 490 ه				
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION							IN 490 g			
Inactive Ingredients										
Ingredient Name							ength			
CITRIC ACID MONOI	HYDRATE (U	NII: 2968PHW8QP)								
FD&C RED NO.40 (U	NII: WZB9127	XOA)								
MAGNESIUM ALUMI	NUM SILICAT	Г Е (UNII: 6 МЗР6 4 V0 NC)								
PHOSPHORIC ACID (UNII: E4GA8884NN)										
POLYSORBATE 20 (UNII: 7T1F30V5YH)										
WATER (UNII: 059QF0KO0R)										
SODIUM BENZOATE (UNII: OJ245FE5EU)										
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)										
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)										
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)										
XANTHAN GUM (UNII: TTV12P4NEE)										
XYLITOL (UNII: VCQ006KQ1E)										
Product Characte	eristics		G							
Color Sc			Score							
-										
Shape			Size							
Shape Flavor		CHERRY	Size Imprint Co	ode						
		CHERRY		ode						
Flavor		CHERRY		ode						
Flavor Contains		CHERRY		ode						
Flavor Contains Packaging					ng Start Date	Marketing	End Da			
Flavor Contains Packaging # Item Code	490 g in 1 BC	CHERRY Package Description DTTLE; Type 0: Not a Combinati	Imprint Co		ng Start Date	Marketing	End Da			
Flavor Contains	0	Package Description DTTLE; Type 0: Not a Combinati	Imprint Co	Marketi 0 1/0 1/20 1	3	Marketing	End Da			
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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.