## SODIUM FLUORIDE 1.1% DENTAL GEL MINT- sodium fluoride gel IPG PHARMACEUTICALS, 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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#### Active Ingredient

1.1% neutral sodium fluoride

Sodium Fluoride Dental Gel 1.1% is a flavored, pH neutral 1.1% sodium fluoride that aids in the prevention of dental decay and helps to treat sensitive teeth.

#### Uses

This is a fluoride dental gel intended for use as a dental caries preventive in adults and pediatric patients.

#### Directions

Use twice a day (morning and evening) in place of regular toothpaste or as recommended by a dentist or a physician.

**Adults and Children 6 Years of Age and Older**: Twist off cap and remove foil seal. Apply at least a1-inch strip of gel onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute. Spit out and rinse mouth thoroughly. Make sure to brush all sensitive areas of the teeth.

**Dosage form and Strengths**: Dental gel containing 1.1% sodium fluoride.

#### Warning

**Contraindications**: Avoid use in patients with known hypersensitivity to fluoride. Do not use in pediatric patients under 6 unless directed by a dentist or physician. Warnings and Precautions: Do no swallow. Keep out of reach of children. Read the prescribing information fully before using this product. If the product is accidentally swallowed in quantities greater than would normally occur with a toothpaste, seek medical help right away. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician. Adverse reactions: To report suspected

**Adverse reactions**, To report suspected adverse reactions, contact IPG Pharmaceuticals at (888) 711-7116 or the FDA at (800) FDA-1088 or www.fda.gov/medwatch.

#### Inactive ingredient

Water, Glycerin, Hydrated Silica, Calcium Carbonate, Xylitol, Sorbitol, Xanthan Gum, Flavor, Yucca Shidigera Root Extract, Quillaja Saponaria Bark Extract, Smilax Aristolochiaefolia Root Extract, Dioscorea Villosa Root Extract, Tocopheryl Acetate, Cocamidopropyl Betaine, Benzyl Alcohol.

**How Supplied/Storage**: 7.4 oz (200gm) in plastic tube. Store at room temperature 59-86°F (15-30°C)

#### Product label

	NDC 71085-074-02	1.1% and a long flooride dashed and						
	NDC /1085-074-02	1.1% neutral sodium fluoride dental gel Indications & Usage: This is a fluoride dental gel intended for use as a dental caries preventive in adult and pediatric patients.						
		Dosage and Administration: Use twice a day (morning and evening) in place of regular toothpaste or as recommended by a dentist or a physician.						
PG		Adults and Children 6 Years of Age and Older: Twist off cap and remove foil seal. Apply at least a 1-inch strip of gel onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute. Spit out and rinse mouth thoroughly. Make sure to brush all sensitive areas of the teeth.						
	Sodium Fluoride Dental Gel 1.1% MINT	Children Under 6 Years of Age: Consult a dentist						
		or physician. Dosage Form and Strengths: Dental gel containing 1.1% Sodium Fluoride.						
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		<ul> <li>Warnings and Precautions: Do not swallow. Keep out of reach of children. Read the prescribing information fully before using this product. If the product is accidentally swallowed in quantities greater than what would normally occur with a toothpaste, seek medical help right away. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this problem to the problem that a verse in the problem persists or worsens. Do not use this problem persists or worsens. Do not use the sections, contact IPG at (880) 711-7116 or the FDA at (800) FDA-1088 or www.fda.gov/medwatch.</li> <li>Description: Sodium Fluoride Dental Gel 1.1% is a flavored, pH neutral 1.1% sodium fluoride that aids in the prevention of dental decay and helps to treat sensitive teeth.</li> <li>Active Ingredients: Sodium Fluoride 1.1%</li> <li>Inactive Ingredients: Water, Glycerin, Hydrated Silica, Calcium Carbonate, Xylitol, Sorbitol, Xanthan Gum, Flavor, Yucca Shidigera Root Extract, Ouilaja Saponaria Bark Extract, Smilax Aristolochiaefolia Root Extract, Dioscorea Villosa Root Extract, Tocopheryl Acetate, Gearmideprepyl Detaine, Berzyl Alcohol.</li> </ul>						
							Rx only	How Supplied/Storage: 7.4 oz (200gm) in plastic tube. Store at room temperature 59-86°F (15-30°C)
								Marutactured in USA for IPG Pharmaceutical, Inc. Tempe, AZ 65281
							7.4 oz (200gm)	





IPG

Sodium Fluoride Dental Gel 1.1%

MINT

GLUTEN-FREE, DYE-FREE, SODIUM LAURYL SULFATE-FREE

**Rx** only

7.4 oz (200gm)

# GLUTEN-FREE, DYE-FREE, SODIUM LAURYL SULFATE-FREE

Sodium Fluoride Dental Gel 1.1%

#### 1.1% neutral sodium fluoride dental gel

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Active Ingredients: Sodium Fluoride 1.1%

Inactive Ingredients: Water, Glycerin, Hydrated Silica, Calcium Carbonate, Xylitol, Sorbitol, Xanthan Gum, Flavor, Yuoca Shidigera Root Extract, Quillaja Saponaria Bark Extract, Smilax Aristolochiaefolia Root Extract, Dioscorea Vilicea Root Extract, Tocopheryl Acetate, Cocamidopropyl Betaine, Benzyl Alcohol.

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Manufactured in USA for IPG Pharmaceuticals, Inc. Temps, AZ 603/1



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### SODIUM FLUORIDE 1.1% DENTAL GEL MINT

sodium fluoride gel

**Product Information** 

Product Type		HUMAN PRESCRIPTION DRUG	ltem C	ode (Source)	NDC	:71085-074	
Route of Admini	stration	ORAL					
Active Ingredi	ent/Active	Moiety					
Ingredient Name Basis of Stre						Strength	
SODIUM FLUORIDI	E (UNII: 8ZYQ14	74W7) (FLUORIDE ION - UNII:Q80V	/PU408O)	FLUORIDE ION	-	1.1 g in 100	
Inactive Ingre	dients						
	S	Strength					
WATER (UNII: 059Q							
GLYCERIN (UNII: PC	C6A3C0OX)						
HYDRATED SILICA	(UNII: Y607T40	8P9)					
CALCIUM CARBON	IATE (UNII: HOG	9379FGK)					
XYLITOL (UNII: VCQ	006KQ1E)						
SORBITOL (UNII: 50	06T60A25R)						
XANTHAN GUM (UN							
YUCCA SCHIDIGER							
QUILLAJA SAPONA							
		<b>OT</b> (UNII: NR100Y25G0)					
DIOSCOREA VILLO							
		(UNII: 9E8X80D2L0)					
COCAMIDOPROPY							
BENZYL ALCOHOL	. (UNII: LKG8494	WBH)					
Packaging							
# Item Code	Рас	kage Description		eting Start Date		eting End Date	
<b>1</b> NDC:71085-074- 02	1 in 1 CARTON		01/14/202	25			
1	200 g in 1 TUE Product	E; Type 0: Not a Combination					
Marketing	Informat	ion					
Marketing Category	Applicat	Application Number or Monograph Citation		Marketing Start I Date		Marketing End Date	
unapproved drug other			01/14/	2025			

Labeler - IPG PHARMACEUTICALS, INC. (080441238)