SODIUM FLUORIDE 1.1% DENTAL GEL BUBBLEGUM- 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.

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 71085-079-02

IPG

Sodium Fluoride Dental Gel 1.1%

BUBBLEGUM

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

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.

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.

Children Under 6 Years of Age: Consult a dentist or physician.

Dosage Form and Strengths: Dental gel containing 1.1% Sodium Fluoride.

Contraindications: Avoid use in patients with known hypersensitivity to fluoride. Do not use in pediatric patients under 6 years unless directed by a dentist or physician.

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 product longer than 4 weeks unless recommended by a dentist or physician.

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

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.

Active Ingredients: Sodium Fluoride 1.1%

Inactive Ingredients: 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)

Manufactured in USA for
IPG Pharmaceuticals, Inc.
Tempe, AZ 85281

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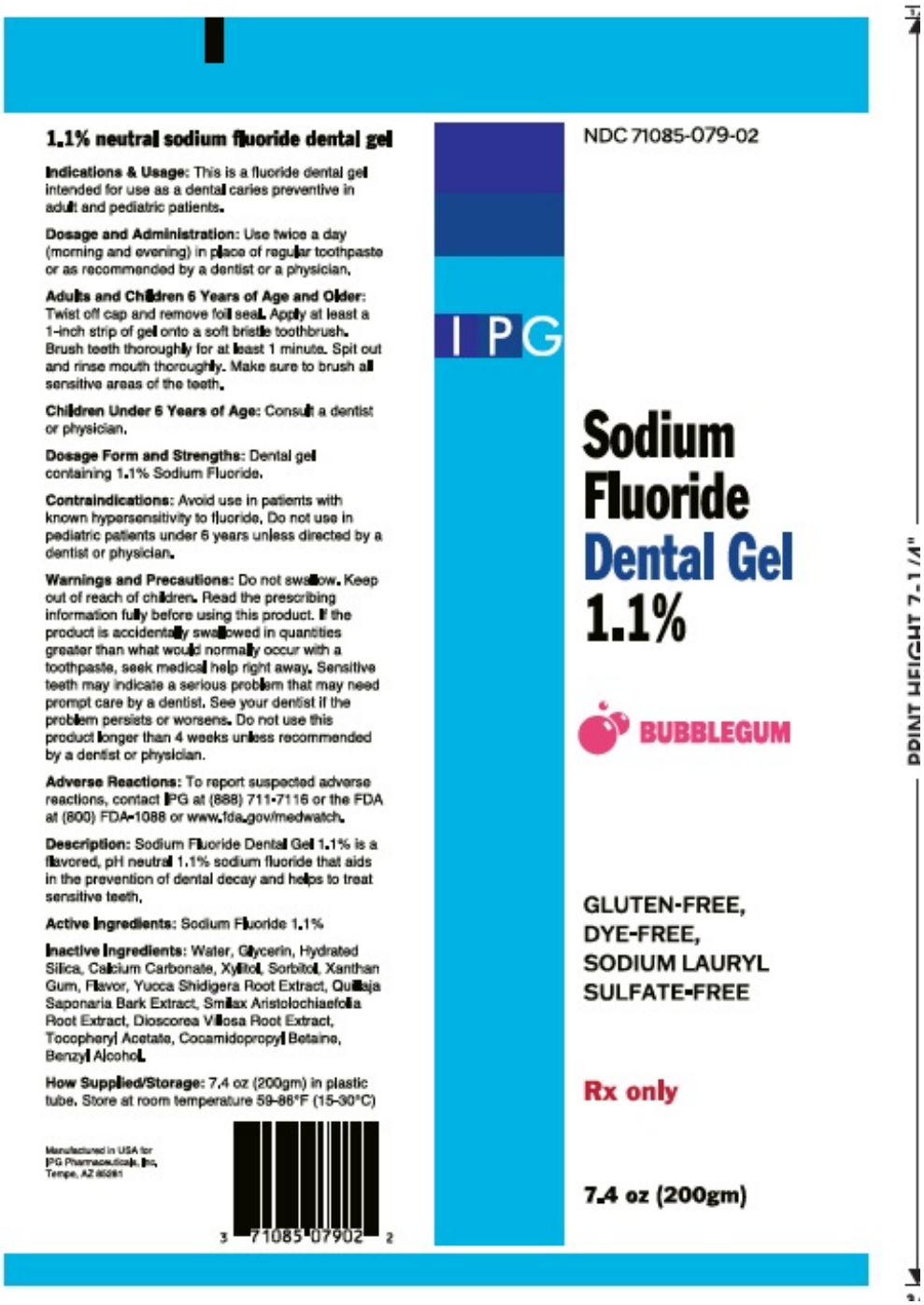
GLUTEN-FREE, DYE-FREE,
SODIUM LAURYL SULFATE-FREE

Sodium Fluoride Dental Gel 1.1%



SODIUM FLUORIDE 1.1% DENTAL GEL BUBBLEGUM

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71085-079
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
YUCCA SCHIDIGERA WHOLE (UNII: 08A0YG3VIC)	
QUILLAJA SAPONARIA BARK (UNII: 8N0K3807ZW)	
SMILAX ARISTOLOCHIIFOLIA ROOT (UNII: NR100Y25G0)	
DIOSCOREA VILLOSA ROOT (UNII: IWY3IWX2G8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71085-079-02	1 in 1 CARTON	07/01/2025	
1		200 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2025	

Labeler - IPG PHARMACEUTICALS, INC. (080441238)

Revised: 7/2025 IPG PHARMACEUTICALS, INC.