NUPRO FLUORIDES WILD CHERRY- sodium fluoride gel
NUPRO FLUORIDES BUBBLE GUM- sodium fluoride gel
Dentsply LLC. Professional Division Trading as "DENTSPLY Professional"

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.

Nupro® Fluorides
Acidulated Phosphate Fluoride (APF) Topical Gel

INDICATIONS AND USAGE

For topical application to aid in the protection against dental caries.

DOSAGE AND ADMINISTRATION

1. Remove cap from bottle, remove induction seal. DO NOT USE IF SEAL IS BROKEN.
2. Replace cap and shake well.
3. Dispense a narrow ribbon of gel into applicator trays.
4. Air dry teeth thoroughly and insert trays in mouth with head tilted slightly forward.
5. Instruct patient to continue light biting action for 1 minute (or up to 4 minutes).
A slight chewing motion enhances interproximal coverage.
6. Use suction throughout treatment.
7. Have patient expectorate after treatment.
8. Instruct patient not to eat, drink, or rinse for 30 minutes.

Recommended Frequency: Not to exceed four 4 treatments per year.

CONTRAINDICATIONS

Hypersensitivity to fluoride.

WARNINGS AND PRECAUTIONS

Do not swallow. Keep out of reach of children.
Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential. Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

OVERDOSAGE

If treatment dose is swallowed [less than 100 mg F], administer milk, limewater, or calcium-type antacid. In case of larger doses [1 pint contains 4.5 grams F ion, which is a lethal dose], use ipecac syrup emetic and immediately seek medical help.

ADVERSE REACTIONS

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

HOW SUPPLIED

2.59% sodium fluoride (1.23% fluoride ion) gel supplied in 12 fl. oz. bottles.

STORAGE

Store at room temperature. Protect from freezing.

SDS WARNINGS

SAFETY DATA SHEET is available on our website, www.dentsplysirona.com, or by contacting Customer Service at 1-800-989-8826.

Warning: Causes skin irritation.
Causes severe eye irritation.

MANUFACTURED FOR

Manufactured For:
DENTSPLY Professional
1301 Smile Way
York, PA 17404 USA
1-800-989-8826

Made in the U.S.A

PRINCIPAL DISPLAY PANEL - Wild Cherry

Dentsply Sirona

Nupro® Fluorides

Acidulated Phosphate Fluoride (APF) Topical Gel

Contains: 2.59% Sodium Fluoride (1.23% Fluoride Ion)

WILD CHERRY

1-Minute Gel Treatment

℞ Only

Indications and Usage: For topical application to aid in the protection against dental caries.

Dosage and Administration:
1. Remove cap from bottle, remove induction seal. DO NOT USE IF SEAL IS BROKEN.
2. Replace cap and shake well.
3. Dispense a narrow ribbon of gel into applicator trays.
4. Air dry teeth thoroughly and insert trays in mouth with head tilted slightly forward.
5. Instruct patient to continue light biting action for 1 minute (or up to 4 minutes). A slight chewing motion enhances interproximal coverage.
6. Use suction throughout treatment.
7. Have patient expectorate after treatment.
8. Instruct patient not to eat, drink, or rinse for 30 minutes.

Recommended Frequency: Not to exceed four 4 treatments per year.

Contraindications: Hypersensitivity to fluoride.

Warnings and Precautions: Do not swallow. Keep out of reach of children.

Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential. Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

Overdosage: If treatment dose is swallowed [less than 100 mg F], administer milk, limewater, or calcium-type antacid. In case of larger doses [1 pint contains 4.5 grams F ion, which is a lethal dose], use ipecac syrup emetic and immediately seek medical help.

Adverse Reactions: Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

How Supplied: 2.59% sodium fluoride (1.23% fluoride ion) gel supplied in 12 fl. oz. bottles.

Store at room temperature.
Protect from freezing.

Warning: Causes skin irritation.
Causes severe eye irritation.

Unvarnished Label Area
1 1/4 x 2 1/4 "

INGREDIENTS:
Sodium Fluoride, Purified Water, Carbopol 974 PNF, Xantham Gum, Phosphoric Acid, Hydrofluoric Acid, Wild Cherry Flavor, Benzoic Acid, Sodium Saccharin, Methyl Paraben, Red #40 Solution

SAFETY DATA SHEET is available on our website, www.dentsplysirona.com, or by contacting Customer Service at 1-800-989-8826.

12fl oz(355ml)
4.4g Fluoride Ion

ReOrder No. 130070
NDC 65222-431-44

Manufactured For:
DENTSPLY Professional
1301 Smile Way
York, PA 17404 USA
1-800-989-8826

Made in the U.S.A
Form No. 587020 Rev. 7 (0617)

PRICIPAL DISPLAY PANEL - Bubble Gum

Dentsply Sirona

Nupro® Fluorides

Acidulated Phosphate Fluoride (APF) Topical Gel

Contains: 2.59% Sodium Fluoride (1.23% Fluoride Ion)

BUBBLE GUM

1-Minute Gel Treatment

℞ Only

Indications and Usage: For topical application to aid in the protection against dental caries.

Dosage and Administration:

1. Remove cap from bottle, remove induction seal. DO NOT USE IF SEAL IS BROKEN.
2. Replace cap and shake well.
3. Dispense a narrow ribbon of gel into applicator trays.
4. Air dry teeth thoroughly and insert trays in mouth with head tilted slightly forward.
5. Instruct patient to continue light biting action for 1 minute (or up to 4 minutes). A slight chewing motion enhances interproximal coverage.
6. Use suction throughout treatment.
7. Have patient expectorate after treatment.
8. Instruct patient not to eat, drink, or rinse for 30 minutes.

Recommended Frequency: Not to exceed four 4 treatments per year.

Contraindications: Hypersensitivity to fluoride.

Warnings and Precautions: Do not swallow. Keep out of reach of children.

Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential. Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

Overdosage: If treatment dose is swallowed [less than 100 mg F], administer milk, limewater, or calcium-type antacid. In case of larger doses [1 pint contains 4.5 grams F ion, which is a lethal dose], use ipecac syrup emetic and immediately seek medical help.

Adverse Reactions: Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

How Supplied: 2.59% sodium fluoride (1.23% fluoride ion) gel supplied in 12 fl. oz. bottles.

Store at room temperature.
Protect from freezing.

Warning: Causes skin irritation.
Causes severe eye irritation.

Unvarnished Label Area
1 ¼ x 2 ¼ "

INGREDIENTS:
Sodium Fluoride, Purified Water, Carbopol 974 PNF, Xantham Gum, Phosphoric Acid, Hydrofluoric Acid, Bubble Gum Flavor, Benzoic Acid, Sodium Saccharin, Methyl Paraben, Red #40 Solution

SAFETY DATA SHEET is available on our website, www.dentsplysirona.com, or by contacting Customer Service at 1-800-989-8826.

12fl oz(355ml)
4.4g Fluoride Ion

ReOrder No. 130072
NDC 65222-451-44

Manufactured For:
DENTSPLY Professional
1301 Smile Way
York, PA 17404 USA
1-800-989-8826

Made in the U.S.A
Form No. 587023 Rev. 7 (0617)

NUPRO FLUORIDES WILD CHERRY

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65222-431
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**

HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY (Wild Cherry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-431-44	7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

NUPRO FLUORIDES BUBBLE GUM

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65222-451
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	pink	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-451-44	7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

Labeler - Dentsply LLC. Professional Division Trading as "DENTSPLY Professional" (144140845)

Establishment

Name	Address	ID/FEI	Business Operations
Dentsply Caulk		083235549	manufacture(65222-431, 65222-451)

Revised: 11/2017 Dentsply LLC. Professional Division Trading as "DENTSPLY Professional"