NUPRO FLUORIDES NAF ORAL SOLUTION MINT- sodium fluoride gel
NUPRO FLUORIDES NAF ORAL SOLUTION APPLE CINNAMON- sodium fluoride gel
NUPRO FLUORIDES NAF ORAL SOLUTION MANDARIN ORANGE- 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
Neutral Sodium Fluoride (NaF) Oral Solution

INDICATIONS AND USAGE

For topical application to aid in the protection against dental caries. The non-acidic fluoride is safe for patients with porcelain, composite restorations, and sealants.

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.
May contain FD&C Yellow No. 6.
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.

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

2.0% sodium fluoride (0.9% 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.

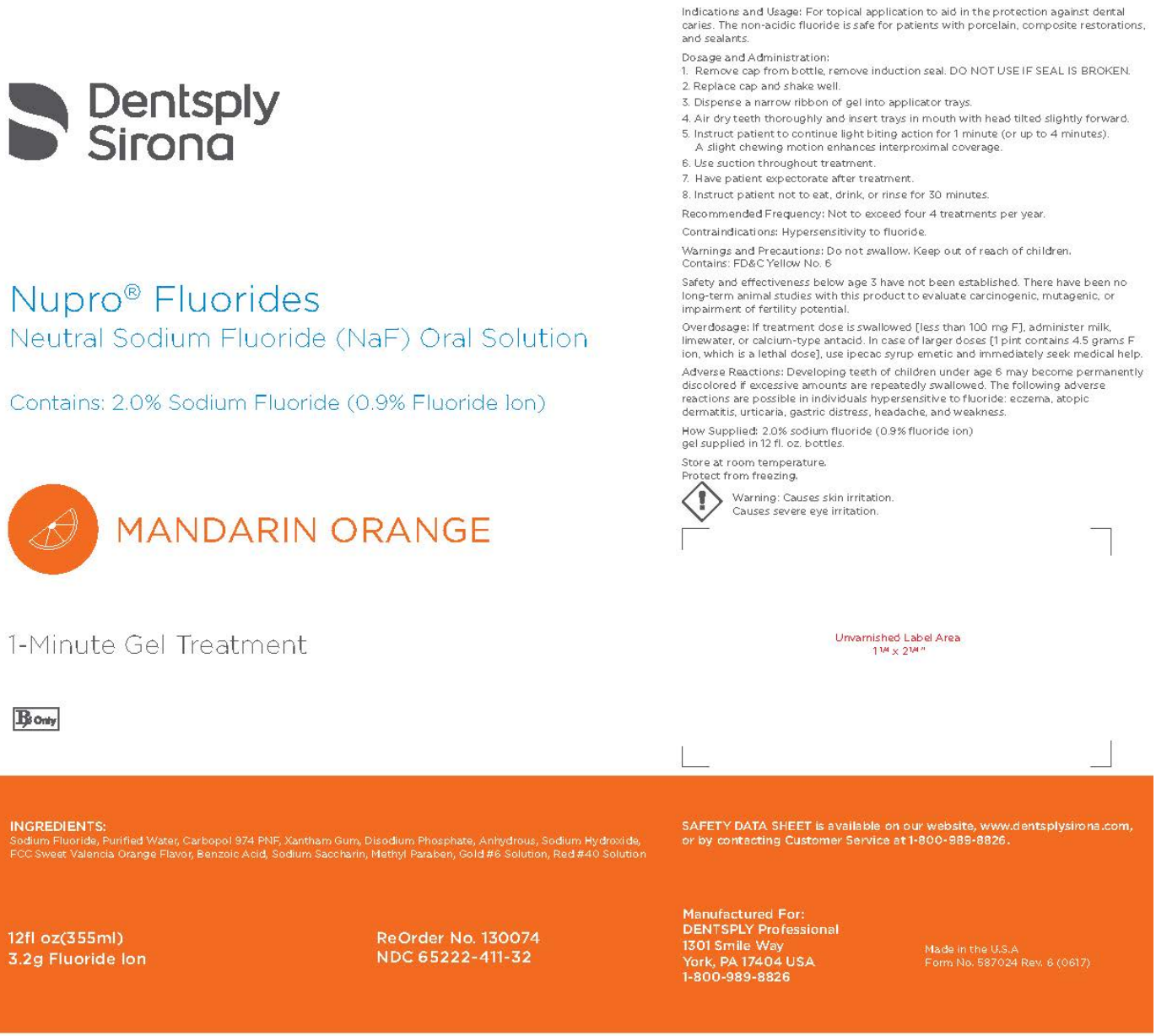
MANUFACTURED FOR

Manufactured For:

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

Made in USA.

PRINCIPAL DISPLAY PANEL - Mandarin Orange



PRINCIPAL DISPLAY PANEL - Mint

Dentsply Sirona

Nupro® Fluorides

Neutral Sodium Fluoride (NaF) Oral Solution

Contains: 2.0% Sodium Fluoride (0.9% Fluoride Ion)

MINT

1-Minute Gel Treatment

Rx Only

Indications and Usage: For topical application to aid in the protection against dental caries. The non-acidic fluoride is safe for patients with porcelain, composite restorations, and sealants.

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.

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: 2.0% sodium fluoride (0.9% 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, Disodium Phosphate, Anhydrous, Sodium Hydroxide, Mint Flavor, Benzoic Acid, Sodium Saccharin, Methyl Paraben, Green Solution (Yellow #10/Blue #1)

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

12fl oz(355ml)
3.2g Fluoride Ion

ReOrder No. 130076
NDC 65222-401-32

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

Made in the U.S.A
Form No. 587025 Rev. 7 (1117)

PRINCIPAL DISPLAY PANEL - Apple Cinnamon

Dentsply Sirona

Nupro® Fluorides

Neutral Sodium Fluoride (NaF) Oral Solution

Contains: 2.0% Sodium Fluoride (0.9% Fluoride Ion)

APPLE CINNAMON

1-Minute Gel Treatment

℞ Only

Indications and Usage: For topical application to aid in the protection against dental caries. The non-acidic fluoride is safe for patients with porcelain, composite restorations, and sealants.

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.
Contains: FD&C Yellow No. 6

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.

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: 2.0% sodium fluoride (0.9% 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, Disodium Phosphate, Anhydrous, Sodium Hydroxide, Apple-Cinnamon Flavor, Benzoic Acid, Sodium Saccharin, Methyl Paraben, Gold #6 Solution, Green Solution (Yellow #10/Blue #1)

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

12fl oz(355ml)
3.2g Fluoride Ion

ReOrder No. 130078
NDC 65222-421-32

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

Made in the U.S.A
Form No. 587026 Rev. 6 (0617)

NUPRO FLUORIDES NAF ORAL SOLUTION MINT

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65222-401
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	GREEN	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-401-32	7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1974	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1974	

NUPRO FLUORIDES NAF ORAL SOLUTION APPLE CINNAMON

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65222-421
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	GREEN	**Score**	
Shape		**Size**	
Flavor	APPLE (Apple Cinnamon)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-421-32	7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1974	04/07/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1974	04/07/2023

NUPRO FLUORIDES NAF ORAL SOLUTION MANDARIN ORANGE

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65222-411
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE	**Score**	
Shape		**Size**	
Flavor	ORANGE (Mandarin Orange)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-411-32	7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1974	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1974	

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

Establishment

Name	Address	ID/FEI	Business Operations
Dentsply Caulk		083235549	MANUFACTURE(65222-401, 65222-411, 65222-421)