

**NUPRO 60 SECOND FLUORIDE FOAM- sodium fluoride aerosol, foam
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™
APF Fluoride Foams**

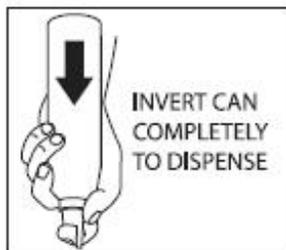
Rx Only

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. Point can toward applicator tray and slowly press nozzle to fill tray. Use one press per arch (foam will expand slightly to fill the tray). Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 1 minute or up to 4 minutes. Remove tray(s) and have patient expectorate excess. Instruct patient not to eat, drink, or rinse for 30 minutes.



RECOMMENDED FREQUENCY

Not to exceed 4 treatments per year.

CONTRAINDICATIONS

Hypersensitivity to fluoride. Acidulated Phosphate Fluoride should not be used for patients with porcelain, composite restorations and sealants.

PRECAUTIONS

Do not swallow. Keep out of reach of children.

Safety and effectiveness below 3 years of age has 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 Acidulated Phosphate Fluoride may dull

porcelain, composite restorations, and sealants.

OVERDOSAGE

If treatment dose is swallowed (or less than 100 mg of Fluoride ion) administer milk, limewater, or calcium-type antacid. In case of larger doses swallowed (more than 100 mg of Fluoride ion) administer ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

ADVERSE REACTIONS

Developing teeth of children under 6 years of age 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

2.73% sodium fluoride (1.23% fluoride ion) foam supplied in 4.4 fl.oz. aerosol container

Store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F) [See USP Controlled room temperature.]

Manufactured for:
DENTSPLY Professional
1301 Smile Way
York, PA 17404

1-800-989-8826

Made in U.S.A.

Danger: Extremely flammable aerosol.

Contains gas under pressure: may explode if heated.

May cause an allergic skin reaction. Causes serious eye damage.

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



PRINCIPAL DISPLAY PANEL - Bubble Gum

Indications and Usage:

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

Dosage and Administration:

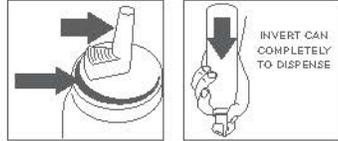
Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. Point can toward applicator tray and slowly press nozzle to fill tray. Use one press per arch (foam will expand slightly to fill the tray). Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 1 minute or up to 4 minutes. Remove tray(s) and have patient expectorate excess. 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. Acidulated Phosphate Fluoride should not be used for patients with porcelain, composite restorations and sealants.

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

Safety and effectiveness below 3 years of age has 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 Acidulated Phosphate Fluoride may dull porcelain, composite restorations, and sealants.

Overdosage:

If treatment dose is swallowed (or less than 100 mg of Fluoride ion) administer milk, limewater, or calcium-type antacid. In case of larger doses swallowed (more than 100 mg of Fluoride ion) administer ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

Adverse Reactions:

Developing teeth of children under 6 years of age 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:

2.73% sodium fluoride (1.23% fluoride ion) foam supplied in 4.4 fl.oz. aerosol container

Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [See USP Controlled Room Temperature]



Danger: Extremely flammable aerosol. Contains gas under pressure; may explode if heated. May cause an allergic skin reaction. Causes serious eye damage.



Nupro® Fluorides

Acidulated Phosphate Fluoride
(APF) Foam

Contains:

2.73% Sodium Fluoride
(1.23% Fluoride Ion)



1-Minute Foam Treatment



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

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

Made in the U.S.A.
13011002 Rev. 4 (0617)

INGREDIENTS:

Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Sodium Fluoride, Oleth-3-Phosphate, Polyethylene Glycol 400, Cetyl Phosphate and Stearic Acid, Cetyl Alcohol, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Monobasic Monohydrate, Bubblegum Flavor, Sodium Saccharin, Sodium Benzoate

4.4 fl oz (125g)
1.54g Fluoride Ion

ReOrder No. 130110
NDC 65222-110-44

PRINCIPAL DISPLAY PANEL - Orange Vanilla

Indications and Usage:

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

Dosage and Administration:

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. Point can toward applicator tray and slowly press nozzle to fill tray. Use one press per arch (foam will expand slightly to fill the tray). Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 1 minute or up to 4 minutes. Remove tray(s) and have patient expectorate excess. 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. Acidulated Phosphate Fluoride should not be used for patients with porcelain, composite restorations and sealants.

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

Safety and effectiveness below 3 years of age has 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 Acidulated Phosphate Fluoride may dull porcelain, composite restorations, and sealants.

Overdosage:

If treatment dose is swallowed (or less than 100 mg of Fluoride ion) administer milk, limewater, or calcium-type antacid. In case of larger doses swallowed (more than 100 mg of Fluoride ion) administer ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

Adverse Reactions:

Developing teeth of children under 6 years of age 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.

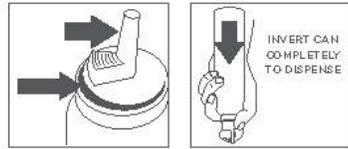
How Supplied:

2.73% sodium fluoride (1.23% fluoride ion) foam supplied in 4.4 fl.oz. aerosol container

Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C - 30°C (59°F - 86°F)
[See USP Controlled Room Temperature]



Danger: Extremely flammable aerosol.
Contains gas under pressure; may explode if heated. May cause an allergic skin reaction. Causes serious eye damage.



Nupro® Fluorides
Acidulated Phosphate Fluoride
(APF) Foam

Contains:

2.73% Sodium Fluoride
(1.23% Fluoride Ion)



1-Minute Foam Treatment



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

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

Made in the U.S.A.
13011302 Rev. 4 (0617)

INGREDIENTS:

Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Sodium Fluoride, Oleth-3-Phosphate, Polyethylene Glycol 400, Cetyl Phosphate and Stearic Acid, Cetyl Alcohol, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Monobasic Monohydrate, Orange Cream Flavor, Sodium Saccharin, Sodium Benzoate

4.4 fl oz (125g)
1.54g Fluoride Ion

ReOrder No. 130113
NDC 65222-113-44

PRINCIPAL DISPLAY PANEL - Spearmint

Indications and Usage:

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

Dosage and Administration:

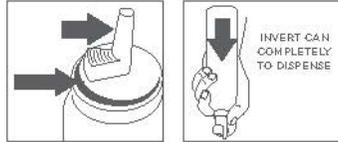
Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. Point can toward applicator tray and slowly press nozzle to fill tray. Use one press per arch (foam will expand slightly to fill the tray). Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 1 minute or up to 4 minutes. Remove tray(s) and have patient expectorate excess. 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. Acidulated Phosphate Fluoride should not be used for patients with porcelain, composite restorations and sealants.

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

Safety and effectiveness below 3 years of age has 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 Acidulated Phosphate Fluoride may dull porcelain, composite restorations, and sealants.

Overdosage:

If treatment dose is swallowed (or less than 100 mg of Fluoride ion) administer milk, limewater, or calcium-type antacid. In case of larger doses swallowed (more than 100 mg of Fluoride ion) administer ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

Adverse Reactions:

Developing teeth of children under 6 years of age 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:

2.73% sodium fluoride (1.23% fluoride ion) foam supplied in 4.4 fl.oz. aerosol container

Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [See USP Controlled Room Temperature]



Danger: Extremely flammable aerosol.
Contains gas under pressure; may explode if heated. May cause an allergic skin reaction. Causes serious eye damage.



Nupro® Fluorides

Acidulated Phosphate Fluoride (APF) Foam

Contains:

2.73% Sodium Fluoride
(1.23% Fluoride Ion)



SPEARMINT

1-Minute Foam Treatment



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

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

Made in the U.S.A
13011402 Rev. 4 (0617)

INGREDIENTS:

Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Sodium Fluoride, Oleth-3-Phosphate, Polyethylene Glycol 400, Cetyl Phosphate and Stearic Acid, Cetyl Alcohol, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Monobasic Monohydrate, Spearmint Flavor, Sodium Saccharin, Sodium Benzoate

4.4 fl oz (125g)
1.54g Fluoride Ion

ReOrder No. 130114
NDC 65222-114-44

PRINCIPAL DISPLAY PANEL - Strawberry

Indications and Usage:

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

Dosage and Administration:

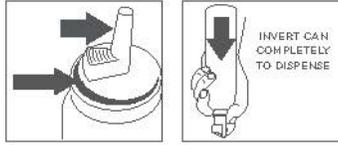
Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. Point can toward applicator tray and slowly press nozzle to fill tray. Use one press per arch (foam will expand slightly to fill the tray). Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 1 minute or up to 4 minutes. Remove tray(s) and have patient expectorate excess. 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. Acidulated Phosphate Fluoride should not be used for patients with porcelain, composite restorations and sealants.

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

Safety and effectiveness below 3 years of age has 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 Acidulated Phosphate Fluoride may dull porcelain, composite restorations, and sealants.

Overdosage:

If treatment dose is swallowed (or less than 100 mg of Fluoride ion) administer milk, limewater, or calcium-type antacid. In case of larger doses swallowed (more than 100 mg of Fluoride ion) administer ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

Adverse Reactions:

Developing teeth of children under 6 years of age 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:

2.73% sodium fluoride (1.23% fluoride ion) foam supplied in 4.4 fl.oz. aerosol container

Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [See USP Controlled Room Temperature]



Danger: Extremely flammable aerosol.
Contains gas under pressure; may explode if heated.
Causes serious eye damage.



Nupro® Fluorides

Acidulated Phosphate Fluoride (APF) Foam

Contains:

2.73% Sodium Fluoride
(1.23% Fluoride Ion)



STRAWBERRY

1-Minute Foam Treatment



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

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

Made in the U.S.A
13011502 Rev. 4 (0617)

INGREDIENTS:

Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Sodium Fluoride, Oleth-3-Phosphate, Polyethylene Glycol 400, Cetyl Phosphate and Stearic Acid, Cetyl Alcohol, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Monobasic Monohydrate, Strawberry Flavor, Sodium Saccharin, Sodium Benzoate

4.4 fl.oz (125g)
1.54g Fluoride Ion

ReOrder No. 130115
NDC 65222-115-44

NUPRO 60 SECOND FLUORIDE FOAM

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65222-110
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
APAFLURANE (UNII: R40P36GDK6)	
BENZALDEHYDE (UNII: TA269SD04T)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-110-44	1 in 1 CARTON	04/01/1997	
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/1997	

NUPRO 60 SECOND FLUORIDE FOAM

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65222-113
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
APAFLURANE (UNII: R40P36GDK6)	
BENZALDEHYDE (UNII: TA269SD04T)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	ORANGE, VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-113-44	1 in 1 CARTON	04/01/1997	
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/1997	

NUPRO 60 SECOND FLUORIDE FOAM

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65222-114
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
APAFLURANE (UNII: R40P36GDK6)	
BENZALDEHYDE (UNII: TA269SD04T)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-114-44	1 in 1 CARTON	04/01/1997	
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/1997	

NUPRO 60 SECOND FLUORIDE FOAM

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65222-115
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
APAFLURANE (UNII: R40P36GDK6)	
BENZALDEHYDE (UNII: TA269SD04T)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65222-115-44	1 in 1 CARTON	04/01/1997	
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/1997	

Labeler - Dentsply Professional (144140845)