

**TOPICAL 60 SEC SODIUM FLUORIDE GRAPE- sodium fluoride aerosol, foam  
Patterson Dental Supply 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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**Patterson® 60-Second Foam Fluoride Grape**

**INDICATIONS AND USAGE**

For topical application to aid in the prevention of dental caries.

Treatment frequency should not exceed 4 treatments per year.

**DOSAGE AND ADMINISTRATION**

Shake can thoroughly for at least 10 seconds before each use.

Hold can completely upside down to dispense. Point can toward applicator tray and slowly press nozzle to fill tray. Dry tooth surface and insert tray(s) into 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.

**DOSAGE FORMS AND STRENGTHS**

This topical foam contains 1.23% fluoride ion.

**CONTRAINDICATIONS**

Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

**WARNINGS AND PRECAUTIONS**

- Do not swallow. Harmful if swallowed.
- Keep out of reach of children.
- Contents under pressure. Do not puncture or incinerate can.
- This product is not intended for home or unsupervised consumer use.
- 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.

Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

**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, urticarial, gastric distress, headache, and weakness.

## **INGREDIENTS**

Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Sodium Fluoride, Crodafos 03A-LQ, Polyethylene Glycol 400, Crodafos MCASA-PA, Cetyl Alcohol, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Monobasic Monohydrate, Artificial Grape Flavor, Sodium Saccharin, Sodium Benzoate

## **STORAGE**

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.]

## **Made in U.S.A.**

0531153LA, R2-012018

## **PRINCIPAL DISPLAY PANEL - 125 g Canister Label**

PATTERSON®  
DENTAL

**NDC# 50227-0531-6**

**Patterson® 60-Second  
Foam Fluoride**

(APF\*) Topical Fluoride Solution  
\*Acidulated Phosphate Fluoride  
1.23% Fluoride Ion (pH 3.5)

**Grape**

**NET WT. 4.4 OZ (125 g)**

Rx Only

Reorder Number  
**088-6143**

Manufactured for:  
Patterson Dental Supply, Inc.  
1031 Mendota Heights Road  
Saint Paul, MN 55120

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



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2.75 X 1  
2D BARCODE AREA  
UNVARNISHED

## TOPICAL 60 SEC SODIUM FLUORIDE GRAPE

sodium fluoride aerosol, foam

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50227-0531
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	123 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Sodium Benzoate (UNII: OJ245FE5EU)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
Cetyl Alcohol (UNII: 936JST6JCN)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
APAFLURANE (UNII: R40P36GDK6)	
Benzaldehyde (UNII: TA269SD04T)	

## Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50227-0531-6	1 in 1 BOX	04/01/1997	
1		125 g in 1 CANISTER; 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** - Patterson Dental Supply Inc (171843584)