

**60 SECOND FLUORIDE GEL- sodium fluoride gel**  
**Darby Dental Supply, LLC**

*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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**Active Ingredient:**

Fluoride Ion 1.23%

Available from 2.09% Sodium Fluoride and Hydrofluoric Acid

**Purpose:**

Fluoride Treatment Gel

**Indications and Usage:**

- A stable thixotropic fluoride treatment gel used to help prevent dental decay.
- For Professional Use Only. This product is not intended for home or unsupervised use.

**Warnings:**

- Keep out of reach of children.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.
- Read directions carefully before using.

**Dosage and Administration:**

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

1. After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

**Other Information:**

Do not store 25°C/77°F. Do not freeze.

## Inactive Ingredients:

Citric Acid, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol. May contain Blue #1, Green #3, Red #3, Red #40, Yellow #5 (tartazine). Yellow #6 as a color additive.



# 60 SECOND FLUORIDE GEL

WITH XYLITOL

Acidulated Phosphate Fluoride Gel  
1.23% Fluoride Ion | Gluten Free

16 oz. (454 g)

**R**Only



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To reorder:

call 800.645.2310 or visit [darby.com](http://darby.com)  
Distributed by: Darby Dental Supply, LLC,  
Jericho, NY 11753

FOR PROFESSIONAL USE ONLY  
IMPORTANT: READ DIRECTIONS FOR PROPER USE

MADE IN THE USA

99092197 08/2019

## 60 SECOND FLUORIDE GEL

sodium fluoride gel

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66467-2250
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	5.6 g in 454 g

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	

### Product Characteristics

<b>Color</b>	purple	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-2250-1	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2019	

**Labeler** - Darby Dental Supply, LLC (825137818)