# 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.

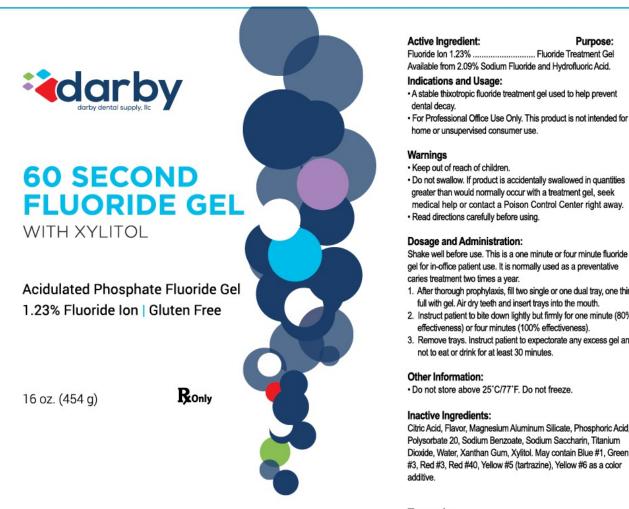
- 1. After thorough prophylaxsis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
- 2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
- 3. Remove trays. Instruct patient 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.



FOR PROFESSIONAL USE ONLY IMPORTANT: READ DIRECTIONS FOR PROPER USE

#### Purpose:

... Fluoride Treatment Gel Available from 2.09% Sodium Fluoride and Hydrofluoric Acid.

- · A stable thixotropic fluoride treatment gel used to help prevent
- · For Professional Office Use Only. This product is not intended for
- greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.

gel for in-office patient use. It is normally used as a preventative

- 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

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To reorder: call 800.645.2310 or visit darby.com Distributed by: Darby Dental Supply, LLC, Jericho, NY 11753

MADE IN THE USA

99092197 08/2019

## 60 SECOND FLUORIDE GEL

sodium fluoride gel

<b>Product Information</b>			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66467-2210
Route of Administration	DENTAL		

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5.6 g in 454 g

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)		
PHOSPHORIC ACID (UNII: E4GA8884NN)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
WATER (UNII: 059QF0KO0R)		
XANTHAN GUM (UNII: TTV12P4NEE)		
XYLITOL (UNII: VCQ006KQ1E)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)		
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

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:66467- 2210-1	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2019	

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	08/01/2019			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

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