

FLUORISHIELD- sodium fluoride gel
Medical Products Laboratories, 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](#).

UNFLAVORED FluoriSHIELD BRAND OF 1.1% Sodium Fluoride Dental Gel

Your dentist has selected for you FluoriShield, a 1.1% Sodium Fluoride product that was specially developed to prevent tooth decay which can occur from xerostomia (dry mouth). Dry mouth can result from radiation therapy, systemic diseases, medications which affect the salivary glands and mouth breathing. Clinical trials have shown that application of topical fluoride gel in the presence of good oral hygiene can prevent or significantly reduce tooth decay which is related to dry mouth. FluoriShield topical fluoride gel can be applied with a custom carrier or tray, directly brushed on, or used with an over denture. Your dentist will prescribe the method that is best suited for your individual needs. The gel is easily dispensed when the bottle is inverted for storing.

STORE INVERTED FOR EASY REMOVAL OF CONTENTS.

Description:

Topical neutral 1.1% sodium fluoride for use as a dental caries preventative in children and adults. This prescription product is not a dentifrice.

Warnings:

DO NOT SWALLOW. As with all medications, this product should be kept out of reach of children.

Overdose:

Accidental ingestion of a usual treatment dose (1-2mgF) is not harmful.

Store at temperature between 68°-77°F (20°-25°C).

CAUTION:

Federal (U.S.A.) law prohibits dispensing without a prescription.

INSTRUCTIONS

Custom Carriers or Trays

Brush and floss your teeth to remove plaque. Adults and children 6 years of age or older: Add one drop of FluoriShield into each tooth area in the custom carrier and spread evenly with the applicator tip of the fluoride bottle. Place carriers over the teeth and let it remain in place for one (1) minute or longer (as directed by your doctor). Expectorate the excess gel. Clean carriers with cold water. Spit out the excess gel in the mouth and do not rinse, eat, or drink for thirty (30) minutes.



Brush On

Brush and floss your teeth to remove plaque. Adults and children 6 years of age or older: Apply a thin ribbon of gel to the toothbrush and spread evenly with the applicator tip of the fluoride bottle. Brush all tooth surfaces and allow fluoride to remain in place for one (1) minute or longer (as directed by your doctor). Clean carriers with cold water. Expectorate the excess gel in the mouth and do not rinse, eat, or drink for thirty (30) minutes.



Overdentures

Brush all tooth surfaces. Clean your dentures. Adults and children 6 years of age or older: Apply one (1) or two (2) drops of FluoriShield to each tooth area in your denture and place the dentures in your mouth. Leave in place for one (1) minute or longer (as directed by your doctor). Expectorate the excess gel in the mouth and do not rinse, eat, or drink for thirty (30) minutes.



TM
MEDICAL PRODUCTS LABORATORIES, INC.
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UNFLAVORED

FluoriSHIELD™

BRAND OF

1.1% Sodium Fluoride Dental Gel

NET WT. 4 oz. (114 grams)

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INDIC: 107335-130-04
 See package insert for additional information.
 Contains Fluoride (F₂Ca) two percent depending on exact presentation.

USE: Dental tissue. Prescription. 1.1% Neutral Sodium Fluoride dental gel. This is not a dentifrice.

CONTAINS: Active ingredient: 1.1% Sodium Fluoride in gel aqueous base.

Precautions: Brush and floss your teeth to remove plaque, tartar, and other 6 years of age or older. Add one drop of Fluorishield into each tooth area in the custom carrier and spread evenly over the application tip of the fluoride toothbrush. Place carrier over the teeth and let it remain in place for one (1) minute of longer (as directed by your doctor). Expectorate the excess gel. Do not eat or drink for 30 minutes. Do not use the product in the mouth area of hot, sore, etc. or other for temporary treatment.

PRECAUTIONS: DO NOT SWALLOW. As with all medications, keep out of reach of the children.
 Store at temperature between 68°-77° F (20°-25°C).

Patient's Name _____

Doctor's Name _____

Date _____



+D725263100.

FLUORISHIELD

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10733-130
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	11 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
HYDROXYETHYL CELLULOSE (4000 MPAS FOR 1% AQUEOUS SOLUTION) (UNII: ZYD53NBL45)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-130-04	66 in 1 CARTON		
1		114 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/29/2009	

Labeler - Medical Products Laboratories, Inc. (002290302)

Revised: 2/2011

Medical Products Laboratories, Inc.