FLUORISHIELD- sodium fluoride gel
Young Dental Manufacturing I, LLC
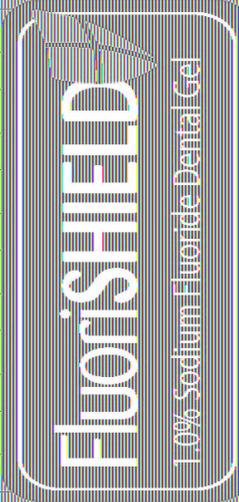

Inactives

Natrosol 250 (Hydroxyethyl Cellulose), Saccharin Sodium

Warning:

PRECAUTIONS: DO NOT SWALLOW. As with all medications, keep out of reach of the children

Directions

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.

FluoriSHIELD

1.1% Sodium Fluoride Dentifrice

See package insert for additional information.

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

USE: Dental Caries Preventative. 1.1% neutral Sodium Fluoride dentifrice. This is not a dentifrice.

CONTAINS: Active ingredient: 1% Sodium Fluoride in an anticvariole base.

Directions: Brush and floss your teeth to remove plaque. Adults and children over 6 years of age: Place a thin ribbon of toothpaste onto toothbrush or apply a pea-sized amount and spread evenly with the applicator tip of the fluoride bottle. Place a pea-sized amount on the brush and brush for one (1) minute two (2) or as directed by your doctor. Expectorate the excess gel. Children rinse with cold water. Spit out the excess gel in the mouth and do not rinse, eat or drink for thirty (30) minutes.

PRECAUTIONS: DO NOT SWALLOW. As with all medications, Keep out of reach of the children. Store at controlled room temperature (77°F/25°C).

Net Wt. 4 oz. (114 grams)
Packed by weight, not volume.

Patient's Name
Doctor's Name
Date

See package insert for additional information.

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FLUORISHIELD

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0273-8011
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	11 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8011-01	114 g in 1 TUBE; Type 0: Not a Combination Product	09/21/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/21/2017	

Labeler - Young Dental Manufacturing I, LLC (006309355)

Registrant - Young Dental Manufacturing I, LLC (006309355)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(0273-8011)

Revised: 12/2018   Young Dental Manufacturing I, LLC