VIVIDSENSIGUARD- sodium fluoride gel, dentifrice Pears on Dental Supply Co.

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.

Active Ingredient

Sodium Fluoride 1.1% (0.5% Fluoride Ion)

Indications

Self-topical neutral 1.1% sodium fluoride for use as a dental caries and hypersensitivity preventative in adults and pediatric patients.

Directions

Adults and children six years of age and older should brush with Vivid SensiGuard™ gel once at bedtime (or as directed). Apply a thin bead of gel to toothbrush and brush for at least one minute, making sure all tooth surfaces are covered. ADULTS: expectorate thoroughly. Do not rinse, drink or eat for at least 30 minutes after use. CHILDREN SIX YEARS OF AGE AND OLDER: expectorate and rinse thoroughly. If recommended by your dental professional, this product can be used in place of your regular toothpaste. Read all instructions and prescribing information before using this product.

Warning

Do not swallow. To avoid ingestion, supervision is required while children are using this product. Swallowing excessive amounts of fluoride could cause dental fluorosis. KEEP OUT OF REACH OF CHILDREN AND INFANTS.

Precautions

Federal (U.S.A.) Law prohibits dispensing without prescription. Store at controlled room temperature 68° - 77° F (20°C - 25°C).

Reorder # M09-1104

Reorder # M09-1105

Manufactured in U.S.A.

Distributed by: Pearson Dental

Sylmar, CA 91342 U.S.A.

Inactive Ingredients

Purified Water, Glycerin, Carboxymethyl Cellulose, Xylitol, Sodium Benzoate, Titanium Dioxide, Sucralose, Sodium Phosphate Monobasic, Calcium Hydroxyapetite, Silica, Sodium Phosphate Dibasic, Flavors.

VIVIDSENSIGUARD

bubble gum.jpg

mint.jpg

INDICATIONS: Self-topical neutral 1.1% sodium fluoride for use as a dental caries and hypersensitivity preventive in adults and pediatric

ACTIVE INGREDIENT: Sodium Fluoride 1.1% (0.5%

INACTIVE INGREDIENT: Purified Water, Glycerin, Carboxymethyl Cellulose, Xylitol, Benzoate, Titanium Dioxide, Sucralose, Sodium Phosphate Monobasic, Calcium Hydroxyapetite, Silica, Sodium Phosphate Dibasic, Flavors.

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Manufactured in U.S.A. Distributed by: Pearson Dental Sylmar, CA 91342 U.S.A. 306533

NDC# 29494-1104-2

Vivid SensiGuard 1.1% Neutral Sodium Fluoride 5,000 PPM Fluoride gel

Bubblegum

Contains Calcium Hydroxyapatite Prescription gel for added protection and cleaning

NET. WT. 2 OZ. (56.7 GRAMS)

NDC# 29494-1105-2

vidSensiGua

Vivid SensiGuard 1.1% Neutral Sodium Fluoride 5,000 PPM Fluoride gel

Prescription gel for added protection and cleaning

Contains Calcium Hydroxyapatite

NET. WT. 2 OZ. (56.7 GRAMS)

INDICATIONS: Self-topical neutral 1.1% sodium fluoride for use as a dental caries and hypersensitivity preventive in adults and pediatric

ACTIVE INGREDIENT: Sodium Fluoride 1.1% (0.5% Fluoride ion)

INACTIVE INGREDIENT: Purified Water, Glycerin, Carboxymethyl Cellulose, Xylitol, Sodium Benzoate, Titanium Dioxide, Sucralose, Sodium Phosphate Monobasic, Calcium Hydroxyapetite, Silica, Sodium Phosphate Dibasic, Flavors.

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Reorder #M09-1105

Manufactured in U.S.A. Distributed by: Pearson Dental 306532 Sylmar, CA 91342 U.S.A.

VIVIDSENSIGUARD

sodium fluoride gel, dentifrice

Product Information

HUMAN PRESCRIPTION DRUG Product Type Item Code (Source) NDC:29494-1105

Route of Administration ORAL, DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYO1474W7) (FLUORIDE ION - UNII: 080 VPU4080)	FLUORIDE ION	11 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
CARBO XYMETHYLCELLULO SE (UNII: 05JZI7B19X)	

TRIBASIC CALCIUM PHO SPHATE (UNII: 91D9 GV0 Z28)
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)
SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SUCRALOSE (UNII: 96K6UQ3ZD4)
SODIUM PHO SPHATE, MONOBASIC (UNII: 3980 JIH2SW)
WATER (UNII: 059QF0KO0R)
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

ı	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:29494-1105-2	56.7 g in 1 TUBE; Type 0: Not a Combination Product	06/13/2016	
I				

NDC# 29494-1105-2

ividSensiGu

Vivid SensiGuard 1.1% Neutral Sodium Fluoride 5,000 PPM Fluoride ge

Reorder# M09-1105

Prescription gel for added protection and cleaning

Contains Calcium Hydroxyapatite

NET. WT. 2 OZ. (56.7 GRAMS)

INDICATIONS: Self-topical neutral 1.1% sodium fluoride for use as a dental caries and hypersensitivity preventive in adults and pediatric

ACTIVE INGREDIENT: Sodium Fluoride 1.1% (0.5% Fluoride ion)

INACTIVE INGREDIENT: Purified Water, Glycerin, Carboxymethyl Cellulose, Xylitol, Sodium Benzoate, Titanium Dioxide, Sucralose, Sodium Phosphate Monobasic, Calcium Hydroxyapetite, Silica, Sodium Phosphate Dibasic, Flavors.

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Reorder #M09-1105

Manufactured in U.S.A. Distributed by: Pearson Dental 306532 Sylmar, CA 91342 U.S.A.

Marketing Information

Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date	
unapproved drug other		06/13/2016		

VIVIDSENSIGUARD

sodium flouride gel, dentifrice

Product	Information
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Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:29494-1104
Route of Administration	ORAL, 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		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
XYLITOL (UNII: VCQ006KQ1E)			
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SODIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW)			
TRIBASIC CALCIUM PHO SPHATE (UNII: 91D9 GV0 Z28)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)			

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	BUBBLE GUM	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:29494-1104-2	56.7 g in 1 TUBE; Type 0: Not a Combination Product	06/13/2016		

INDICATIONS: Self-topical neutral 1.1% sodium fluoride for use as a dental caries and hypersensitivity preventive in adults and pediatric patients **ACTIVE INGREDIENT:** Sodium Fluoride 1.1% (0.5% Fluoride ion)

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Reorder #M09-1104

Manufactured in U.S.A. Distributed by: Pearson Dental 306533 Sylmar, CA 91342 U.S.A.

NDC# 29494-1104-2

NET. WT. 2 OZ. (56.7 GRAMS) Prescription gel for added protection and cleaning **Contains Calcium Hydroxyapatite**

Vivid SensiGuard 1.1% Neutral Sodium Fluoride 5,000 PPM Fluoride gel

Marketing Information

Marketing Category Application Number or Monograph Citation Marketing Start Date **Marketing End Date** unapproved drug other 06/13/2016

Labeler - Pearson Dental Supply Co. (082874108)

Revised: 7/2016 Pearson Dental Supply Co.