

SENSITIVITY AND GUM- stannous fluoride paste, dentifrice DG Health (Rexall)

5820069 Rexall Sensitivity & Gum

Active ingredient

Stannous fluoride 0.454% w/w (0.15% w/v fluoride ion)

Purpose

Anticavity, Antigingivitis, Antihypersensitivity

Uses

aids in the prevention of dental cavities * helps interfere with the harmful effects of plaque associated with gingivitis * builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact

Warnings

When using this product, if irritation occurs discontinue use.

Stop use and ask a dentist if: * the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist * pain/sensitivity still persists after 4 weeks of use * gingivitis, bleeding, or redness persists for more than 2 weeks * you have painful or swollen gums, pus from the gum line, loose teeth, or increasing space between teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children

If more than is used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years of age and older: apply at least a 1-inch strip of the product unto a soft bristle toothbrush * brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing. * **children under 12 years of age:** consult a dentist or doctor.

Other information

products containing stannous fluoride may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist. * this product is specifically formulated to help prevent staining. * store below 30°C (86°F)

Inactive ingredients

glycerin, water, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, cellulose gum, cocamidopropyl betaine, sodium saccharin

Principal Display Panel

<p>Drug Facts</p> <p>Active ingredient Stannous fluoride 0.454% w/w (0.15% w/v fluoride ion).....Anticavity, Antigingivitis, Antihypersensitivity</p> <p>Purpose Anticavity, Antigingivitis, Antihypersensitivity</p> <p>Uses • aids in the prevention of dental cavities • helps interfere with the harmful effects of plaque associated with gingivitis • builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact</p> <p>Warnings When using this product, if irritation occurs discontinue use.</p> <p>Stop use and ask a dentist if: • the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist • pain/sensitivity still persists after 4 weeks of use • gingivitis, bleeding, or redness persists for more than 2 weeks • you have painful or swollen gums, pus from the gum line, loose teeth, or increasing space between teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.</p> <p>Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>Directions adults and children 12 years of age and older: apply to at least a 1-inch strip of the product onto a soft bristle toothbrush • brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing. • children under 12 years of age: Consult a dentist or doctor.</p> <p>Other information products containing stannous fluoride may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist. • this product is specifically formulated to help prevent staining.</p> <p>Inactive ingredients glycerin, water, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, cellulose gum, cocamidopropyl betaine, sodium saccharin</p>	<p>*This product is not manufactured or distributed by Block Drug Company, Inc., owner of the registered trademark Sensodyne®.</p>
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <h1 style="margin: 0;">SENSITIVE</h1> <h2 style="margin: 0;">TOOTHPASTE WITH FLUORIDE</h2> <p style="font-size: small;">For Sensitive Teeth, Gingivitis and Cavity Protection Improves Gum Health</p> </div> <div style="text-align: center;"> <p>Compare to the active ingredient of Sensodyne® Sensitivity & Gum*</p> <h3 style="margin: 0;">SENSITIVITY & GUM</h3>  <p>NET WT 2.3 OZ (65.2 g)</p> </div> <div style="text-align: center;"> <p>WHITENING</p> </div> </div>		
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<p>Formulated to relieve tooth sensitivity and improve gum health</p> <ul style="list-style-type: none"> • Builds a protective layer over sensitive areas • Targets and helps remove plaque bacteria to help reduce swollen, bleeding gums • Relieves tooth sensitivity** • Improves gum health <p><small>** With brushing twice daily</small></p>	<p style="font-size: x-small;">DISTRIBUTED BY OLD EAST MAIN CO. 100 MISSION RIDGE GOODLETTSVILLE, TN 37072</p> <p style="font-size: x-small;">MADE IN USA OF DOMESTIC AND IMPORTED INGREDIENTS</p> <div style="border: 1px solid black; padding: 2px; text-align: center; font-size: x-small;"> <p>100% Satisfaction Guaranteed! (888) 309-9030</p> </div>	<p style="text-align: center; font-size: x-small;">A1684</p>  <p style="text-align: center; font-size: x-small;">0 67990 00899 7</p> <p style="text-align: right; font-size: x-small; writing-mode: vertical-rl; transform: rotate(180deg);">2821069RT 5820069</p>

SENSITIVITY AND GUM

stannous fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-569
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-569-19	1 in 1 CARTON	01/11/2024	
1		65.2 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/11/2024	

Labeler - DG Health (Rexall) (068331990)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(55910-569) , pack(55910-569)

Revised: 1/2024

DG Health (Rexall)