BIOMIN RESTORE PLUS- sodium fluoride paste, dentifrice DRCOLLINS, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BioMin Restore Plus

Purpose

Anticavity & Sensitivity Relief

Indications for Use

Fluoride dentifrice for use in the prevention and treatment of dental sensitivity.

Instructions for Use

Remove foil cover from nozzle, do not use if this seal has been broken. Brush twice daily for 2 minutes, ideally first thing in the morning and last thing at night, swirl the foamy dentifrice around your mouth for 30 seconds, and spit out. Do not swallow. Avoid rinsing your mouth with water after brushing. Replace cap after use to keep dentifrice dry.

Warnings and Precautions

Continued tooth pain or sensitivivity could indicate an inherent problem that needs professional diagnosis. If symptoms persist consult your dentist. If irritation occurs, discontinue use.

Keep Out of Reach of Children

Keep Out of Reach of Children. For Adults Use Only.

Warning

DO NOT USE IF YOU ARE ALLERGIC TO ANY OF THE INGREDIENTS

Active Ingredient

Sodium Fluoride. (Fluoride concentration is 530µg/g by weight.)

Inactive Ingredients

Glycerin, Silica, PEG 400, Cocomidapropyl Betaine, Sodium Methyl Cocoyl Taurate, Titanium Dioxide, Aroma, Carbomer, Potassium Acesulfame.

Dosage & Administration

Net Wt. 3.35oz (100g)

75ml e / 100g e / 3.5oz e.

Storage & Handling

Storage temperatures limit: up to 30°C.

Do ot use if package is damaged.

Carton



SLS FREE

SENSITIVITY RELIEF

FLUORIDE DENTIFRICE

Net Wt. 3.35oz (100q)





SLS FREE

SENSITIVITY RELIEF

FLUORIDE DENTIFRICE

Net Wt. 3.35oz (100g)



Refreshing Fluoride Mint Biomimetic Dentifrice with BioMin® F Protection

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75ml e / 100g e / 3.5oz e (🐼) 🔏 30°C



PMCB0000

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www.biomin.co.uk

WARNINGS AND PRECAUTIONS

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Tube Label



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REF PMTB0053

BIOMIN RESTORE PLUS

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77055-100
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.53 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
SO DIUM METHYL CO CO YL TAURATE (UNII: JVL98CG53G)	0.0055 g in 1 g

GLYCERIN (UNII: PDC6A3C0OX)	0.573 g in 1 g
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)	0.0055g in $1g$
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	0.156 g in 1 g
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	0.18 g in 1 g
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	0.0075 g in 1 g
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	0.004 g in 1 g
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	0.01g in 1g
PEPPERMINT (UNII: V95R5KMY2B)	0.0085g in $1g$

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:77055-100-01	1 in 1 CARTON	05/01/2020	
1	100 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 final	part355	05/01/2020		

Labeler - DRCOLLINS, INC. (022002951)

Revised: 4/2020 DRCOLLINS, INC.