

**REXALL RESTORE AND DEFEND SENSITIVE WHITENING- stannous fluoride paste, dentifrice
Old East Main CO.**

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.

Rexall™ SENSITIVE TOOTHPASTE WITH FLUORIDE - WHITENING

Drug Facts

Active ingredient

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

Purpose

Anticavity, Antihypersensitivity

Uses

Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact • aids in the prevention of dental cavities

Warnings

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

• **Keep out of reach of children under 12 years of age.** If more than amount used for brushing is accidentally swallowed, seek medical help or contact a Poison Control Center immediately.

Directions

• **Adult and children 12 years & older:** apply at least a 1-inch strip of the product onto a soft bristle toothbrush • brush teeth thoroughly for at least one minute, twice a day (morning and evening) and not more than 3 times a day or as recommended by a dentist or physician. 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. Store at room temperature 68-77°F (20-25°C)

Inactive ingredients

glycerin, hydrated silica, treated water, PEG-8, PEG-32, sodium lauryl sulphate, tetrasodium pyrophosphate, flavor, trisodium phosphate, titanium dioxide, cocamidopropyl betaine, sodium saccharin, xanthan gum, polyacrylic acid, benzyl alcohol

Since 1903

TOOTHPASTE WITH FLUORIDE

- For sensitive teeth and cavity protection
- Great for everyday use

Brushing twice a day with Rexall™ Restore & Defend Sensitive Toothpaste helps repair sensitive teeth and protect against painful sensitivity.

- **Provides daily relief & protection for sensitive teeth***
- **Contains fluoride for cavity protection**
- **Removes stains for whiter teeth**
- **Freshens breath**

100% Satisfaction Guaranteed!

(888) 309-9030

*With brushing twice daily

DISTRIBUTED BY OLD EAST MAIN CO.
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

PRODUCT OF INDIA

Packaging

OUTER PACKAGE LABEL



Rexall

SENSITIVE TOOTH PASTE WITH FLUORIDE

NET WT 3.4 OZ (96.4 g)



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INNER PACKAGE LABEL

6.4 mm BG Area can be extend but after formation of the tube will come on back panel

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DISTRIBUTED BY OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072 PRODUCT OF INDIA 1821041R1

REXALL RESTORE AND DEFEND SENSITIVE WHITENING

stannous fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-820
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	4.54 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-820-01	1 in 1 BOX	03/21/2022	
1		96.4 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	03/21/2022	

Labeler - Old East Main CO. (068331990)

Registrant - Ashtel Studios Inc. (148689180)

Revised: 3/2022

Old East Main CO.