

**REXALL TRAVEL TOOTHBRUSH AND TOOTH-PASTE- sodium monofluorophosphate
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™ Travel Toothbrush and Toothpaste

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76%
(0.13% w/v fluoride ion)

Purpose

Anticavity toothpaste

Inactive ingredients:

Sorbitol, Hydrated Silica, Treated Water (Aqua), Poly Ethylene Glycol 1500 (PEG-32), Sodium Lauryl Sulphate, Glycerin, Flavor, Cellulose Gum, Titanium Dioxide (CI 77891), Tetra Sodium Pyrophosphate, Sodium Benzoate, Benzyl Alcohol, Sodium Saccharin, Trisodium Phosphate

Use

helps protect against cavities

Warnings:

Keep out of the reach of children under 6 yrs. of age.

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

Directions

- **Adults and children 2 years of age & older:** brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.
- **Children 2 to 6 years:** use only a pea-sized amount and supervise child's brushing and rinsing to minimize swallowing
- **Children under 2 years:** ask a dentist or physician.

Questions or comments?

Call toll free **1-866-4-REXALL**

Conforms to airline carry-on regulations

TO ASSEMBLE TOOTHBRUSH:

Insert plug end of toothbrush into handle for use.

Insert brush end of toothbrush into handle for storage.

Visit us at : Rexall.com

Since 1903 Rexall™ is a Trademark of Rexall Sundown, Inc.

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

MADE IN INDIA

Packaging

KIT COMPONENT LABEL

Visit us at: Rexall.com or call 1-866-4-REXALL
Since 1903 Rexall™ is a trademark of Rexall Sundown, Inc.

Since 1903
Rexall™

Toothpaste

Cavity Protection

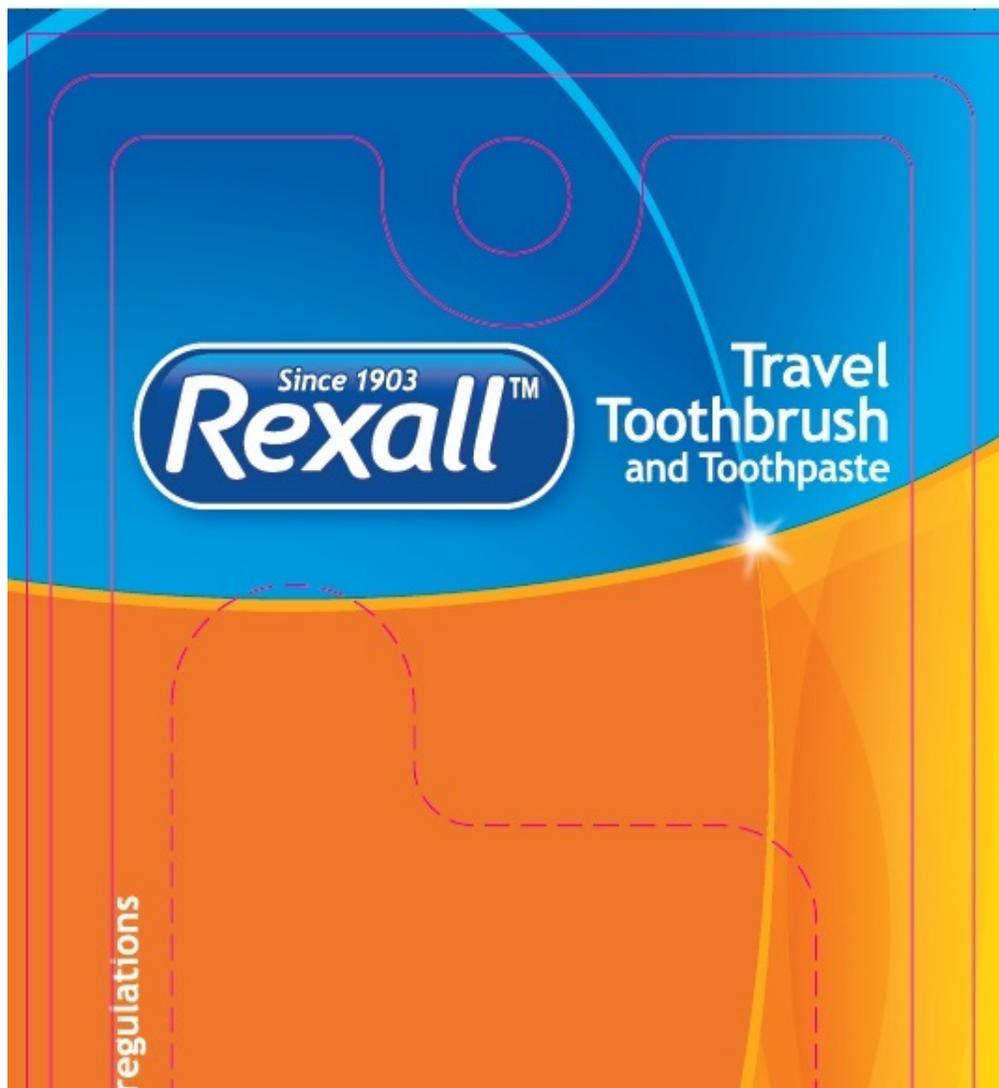
NET WT 0.85 OZ (24 g)

- Strengthens teeth with active fluoride

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

Drug Facts	Drug Facts (continued)
<p>Active ingredient Purpose Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion)... Anticavity toothpaste</p>	<p>If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.</p>
<p>Inactive ingredients: Sorbitol, Hydrated Silica, Treated Water (Aqua), Poly Ethylene Glycol 1500 (PEG-32), Sodium Lauryl Sulphate, Glycerin, Flavor, Cellulose gum, Titanium Dioxide (CI 77891), Tetra Sodium Pyrophosphate, Sodium Benzoate, Benzyl Alcohol, Sodium Saccharin, Trisodium Phosphate</p>	<p>Directions</p> <ul style="list-style-type: none"> • Adults and children 2 years of age & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. • Children 2 to 6 years: use only a pea-size amount and supervise child's brushing and rinsing to minimize swallowing • Children under 2 years: ask dentist or physician.
<p>Use helps protect against cavities</p>	<p>Questions or comments? Call toll free 1-866-4-REXALL</p>
<p>Warnings: ▶ Keep out of the reach of children under 6 yrs. of age.</p>	

KIT LABEL

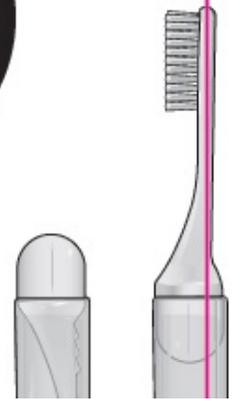


Conforms to airline carry-on

1 TRAVEL TOOTHBRUSH
1 REXALL™ CAVITY PROTECTION TOOTHPASTE

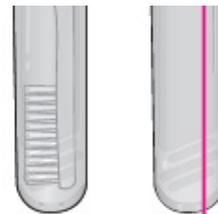
Since 1903
Rexall™

**Travel
Toothbrush**



TOOTHBRUSH

with Rexall™ Toothpaste



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Insert brush end of toothbrush into handle for storage.

Rexall™ Cavity Protection Toothpaste

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MADE IN INDIA

A0158



REXALL TRAVEL TOOTHBRUSH AND TOOTH-PASTE

sodium monofluorophosphate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-087
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-087-01	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	10/12/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	24 g

Part 1 of 1

REXALL CAVITY PROTECTION TOOTH-PASTE

sodium monofluorophosphate paste, dentifrice

Product Information

Item Code (Source)	NDC:55910-090
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Route of Administration	DENTAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	

WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		24 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	10/12/2022	

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OTC monograph final	part355	10/12/2022	

Labeler - Old East Main CO. (068331990)

Registrant - Ashtel Studios, Inc. (148689180)