

**REXALL SENSITIVE EXTRA WHITENING- potassium nitrate, sodium 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.*

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**Rexall™ SENSITIVE TOOTHPASTE WITH FLUORIDE - EXTRA WHITENING**

***Drug Facts***

***Active ingredients***

Potassium Nitrate (5%)  
Sodium Fluoride 0.24% (0.15% w/v fluoride ion)

***Purpose***

Antihypersensitivity  
Anticavity

***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***

• **Adults 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 two minutes, preferably after each meal or at least twice a day (morning and evening) 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

Store at room temperature 68-77°F (20-25°C)

## Inactive ingredients

Sorbitol, Hydrated Silica, Treated water, PEG-32, Sodium Lauryl Sulfate, Glycerin, Flavor, Cellulose Gum, Tetrasodium Pyrophosphate, Titanium Dioxide, Benzyl Alcohol, Sodium Benzoate, Trisodium Phosphate, Sodium Saccharin, Sodium Hydroxide

## MAXIMUM STRENGTH

### TOOTHPASTE WITH FLUORIDE

- For sensitive teeth and cavity protection

**Brushing twice a day builds a protective coating against painful sensitivity.**

- **Contains potassium nitrate, clinically proven to reduce painful sensitivity**
- **Fluoride for cavity protection**
- **Great taste keeps mouth feeling fresh & clear**

**Since 1903 Rexall™ is a trademark of Rexall Sundown, Inc.**

**100% satisfaction Guaranteed!**

(888) 309-9030

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE,  
GOODLETTSVILLE, TN 37072

MADE IN INDIA

## Packaging

### OUTER PACKAGE LABEL



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C. No. DNH/COS/DNH/52

A0812



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**Drug Facts (continued)**

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**INNER PACKAGE LABEL**

<b>Drug Facts</b>	<b>Purpose</b>
Potassium nitrate 5%, Antihypersensitivity Sodium fluoride 0.24% (0.15% w/w fluoride ion).....Anticavity	
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<b>Directions</b>	<b>Warnings</b>
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<b>Uses</b>	<b>Other Information</b>
Built increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact • aids in the prevention of dental cavities	Store at room temperature 68-77°F (20-25°C)

**REXALL SENSITIVE EXTRA WHITENING**

potassium nitrate, sodium fluoride paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-817
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.24 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS</b> (UNII: SX01TZO3QZ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-817-01	1 in 1 BOX	03/21/2022	
1		113 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 not final	part356	03/21/2022	

**Labeler** - Old East Main CO. (068331990)**Registrant** - Ashtel Studios Inc. (148689180)