COLGATE ULTRA RELIEF- sodium fluoride and potassium nitrate paste, dentifrice
Colgate-Palmolive Company

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.

Colgate® Ultra Relief

Drug Facts

Active ingredients	*Purpose*
Potassium Nitrate 5%	Antisensitivity
Sodium Fluoride 0.24% (0.14% w/v fluoride ion)	Anticavity

Uses

- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact
- helps protect against cavities

Warnings

When using this product, if pain/sensitivity still persists after 4 weeks of use, please visit your dentist.

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.

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.

Directions

adults and children 12 years of age and older	apply 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) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
children under 12 years	consult a dentist or physician

Inactive ingredients

Water, Glycerin, Hydrated Silica, Sorbitol, PEG-12, PVM/MA Copolymer, Sodium Lauryl Sulfate, Flavor, Trisodium Phosphate, Poloxamer 407, Sodium Hydroxide, Sodium Saccharin, Cellulose Gum, Xanthan Gum, Blue 1.

Questions?

1-800-468-6502

Dist. by:
***COLGATE-PALMOLIVE** CO.*

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 60 g Tube Carton

Colgate®
Anticavity Toothpaste for Sensitive Teeth

ULTRA
RELIEF

Relieves tooth sensitivity + Strengthens enamel
gel

NET WT 2.1 OZ (60 g)

COLGATE ULTRA RELIEF

sodium fluoride and potassium nitrate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35000-992
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.4 mg in 1 g

POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	189.046 mg in 1 g
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
BUTYL ESTER OF METHYL VINYL ETHER/MALEIC ANHYDRIDE COPOLYMER (125000 MW) (UNII: 389H2R62BD)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	BLUE	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:35000-992-21	1 in 1 CARTON	10/16/2020	
1		60 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	10/16/2020	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 10/2020 Colgate-Palmolive Company