

**DOLLAR GENERAL MAXIMUM STRENGTH- fluoride paste, dentifrice**

**Dolgenercorp LLC**

*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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**Drug Facts**

**Active ingredients / Purpose**

Potassium nitrate 5%.....Antihypersensitivity

Sodium fluoride 0.24% (0.15% w/v fluoride ion).....Anticavity

**Uses**

aids in the prevention of dental cavities

**If pain/sensitivity still persists** after 4 weeks of use, please visit your dentist. **Stop use and see your doctor** if the problem 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 product onto a soft bristle toothbrush. Brush teeth thoroughly for at least one minute, preferably after each meal or at least twice a day (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth.

Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. **Children under 12 years of age:** consult a dentist or a doctor.

**Other Information**

**Store in a cool dry place. Keep tube capped when not in use.**

**Inactive ingredients**

cocamidopropyl betaine, flavor, glycerin, hydrated silica, PEG-8, sodium hydroxide, sodium methyl cocoyl taurate, sodium saccharin, sodium tripolyphosphate, sorbitol, titanium dioxide, water, xanthan gum

mm1.jpg



mm2.jpg



# DOLLAR GENERAL MAXIMUM STRENGTH

fluoride paste, dentifrice

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-320
Route of Administration	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.24 g in 100 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5.0 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

## Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-320-39	1 in 1 CARTON		
1	NDC:55910-320-32	113 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/20/2011	

**Labeler** - Dolgencorp LLC (068331990)

**Registrant** - Lornamead (126440440)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(559 10-320) , pack(559 10-320)

Revised: 11/2012

Dolgencorp LLC