GREEN GUARD TOPICAL PAIN RELIEF- lidocaine hci spray
Ultra Distributors Inc

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.

GREEN GUARD®
Burn spray

Active ingredient

Lidocaine HCI 2.0%

Purpose

Topical pain relief

Uses

Temporary pain relief associated with minor burns

Warnings

For external use only.

Do not use

- in large quantities, particularly over raw or blistered areas
- near eyes, if this happens rinse thoroughly with water

Stop use and ask a doctor

if condition worsens or persists for more than 7 days or clears up and returns.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- spray an even layer of burn spray over cleaned affected area not more than 3-4 times daily
- not to be used on Children under 12 years of age

Inactive ingredients

glycerin, hydroxypropyl methylcellulose, melaleuca alterniflia (tea tree) leaf oil, octoxynol 9,PEG-40 hydrogenated castor oil, phenoxyethanol, propylene glycol, triethanolamine, water

Questions or comments?

1-800-869-6970

Topical Pain Relief

Relieves pain of minor burns

Store at 68°-77°F (20°-25°C)

GREEN GUARD TOPICAL PAIN RELIEF

lidocaine hci spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78495-132
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

TROLAMINE (UNII: 9O3K93S3TK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78495-132-01	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/19/2020	

Labeler - Ultra Distributors Inc (007160073)

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