ARAMARK BURN- lidocaine hcl spray Western First Aid Safety DBA Aramark

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.

Aramark Burn Spray Drug Facts

Active ingredients

Lidocaine HCl 2.0%

Purpose

Topical pain relief

Uses

Temporary pain relief for 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 continues for more than 7 days or clears up and returns Keep out of reach of children. If swallowed get medical help or contact Poison Control Center right away Directions for adults and children 2 years of age and older: spray an even layer of burn spray over cleaned affected area not more than 3-4 times daily for children under 2 years of age consult a physician

Inactive ingredients

aloe vera, germaben II, propylene glycol, purified water

PRINCIPAL DISPLAY PANEL - 3 oz. bottle

aramark

First Aid Burn Spray

For Temporary Pain Relief and Minor Burns

4 fl. oz. (118 mL)

Reorder no. 50004ARA

MANUFACTURED FOR:

Aramark

Lenexa, KS 66219 886-362-2691



First Aid Burn Spray

For Temporary Pain Relief and Minor Burns

Cools and soothes damaged skin without trapping heat and dries without leaving skin feeling sticky

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4 fl. oz. (118ml) Reorder no. 50004ARA MANUFACTURED FOR:

Aramark Lenexa, KS 66219 886-362-2691

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ARAMARK BURN

lidocaine hcl spray

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:81238-5100

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			
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:81238- 5100-3	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/15/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/15/2021		

Labeler - Western First Aid Safety DBA Aramark (043861524)

Registrant - Western First Aid Safety DBA Aramark (043861524)

Establishment				
Name	Address	ID/FEI	Business Operations	
Safetec of America, Inc.		874965262	MANUFACTURE(81238-5100)	

Revised: 6/2021 Western First Aid Safety DBA Aramark