

## **UNISHIELD FIRST AID BURN- lidocaine hcl spray**

### **Unishield**

*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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### **Unishield First Aid Burn Spray**

#### ***Active ingredient***

Lidocaine HCL 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 over 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 alternifolia (tea tree) leaf oil, octoxynol 9, PEG-40 hydrogenated castor oil, phenoxyethanol, propylene glycol, triethanolamine, water

**Questions or comments** □

1-800-480-5855

**Package Label - Principal Display Panel**

**Drug Facts**

Active ingredient	Purpose
Lidocaine HCl 2.0% .....	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 alternifolia (tea tree) leaf oil, octoxynol 9, PEG-40 hydrogenated castor oil, phenoxyethanol, propylene glycol, triethanolamine, water

**Questions or comments?** 1-800-480-5855

**UNISHIELD FIRST AID BURN**

lidocaine hcl spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49314-0002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>OCTOXYNOL 9</b> (UNII: 7JPC6Y25QS)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49314-0002-1	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/20/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/20/2023	

**Labeler** - Unishield (790677053)

Revised: 3/2023

Unishield