

NORTH BURN RELIEF- lidocaine hydrochloride spray
Honeywell Safety Products USA, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

0498-0221 & 0498-0201: Burn Relief Spray

Active ingredient

Lidocaine HCl 2%

Purpose

External analgesic

Uses

temporarily relieves pain due to minor burns

Warnings

For external use only

Do not use

over large areas of the body, particularly over raw surfaces or blistered areas

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

Keep out of the reach of children

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

Directions

- **adults and children 2 years of age and older:** apply to affected area not more than 3 to 4 times daily
- **children under 2 years of age:** ask a doctor

Other information

- store at room temperature

Inactive ingredients

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine

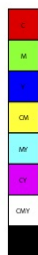
Questions or comments?

1-800-430-5490

Principal Display Panel



032204 Rev. H North Burn Relief Spray
Two Color: Red PMS 032 & Black



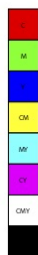
Honeywell 032204  BURN RELIEF SPRAY Lidocaine HCl <i>External analgesic</i> 2 FL OZ (59 mL) <div style="border: 1px solid black; padding: 2px; display: inline-block;">Package Not Child Resistant</div> ANSI Z308.1-2003  8 2 18 12 0 14 9 9 9	Drug Facts <table border="1"> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Lidocaine HCl 2%</td> <td>External analgesic</td> </tr> <tr> <td colspan="2">Use temporarily relieves pain due to minor burns</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only</td> </tr> <tr> <td colspan="2">Do not use over large areas of the body, particularly over raw surfaces or blistered areas</td> </tr> <tr> <td colspan="2">When using this product avoid contact with the eyes</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if - condition worsens</td> </tr> <tr> <td colspan="2">- symptoms last more than 7 days</td> </tr> <tr> <td colspan="2">- condition clears up and occurs again within a few days</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2">- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily</td> </tr> <tr> <td colspan="2">- children under 2 years of age: ask a doctor</td> </tr> <tr> <td colspan="2">Other information store at room temperature</td> </tr> <tr> <td colspan="2">Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine</td> </tr> <tr> <td colspan="2">Questions or comments? 1-800-430-5490</td> </tr> </table>	Active ingredient	Purpose	Lidocaine HCl 2%	External analgesic	Use temporarily relieves pain due to minor burns		Warnings		For external use only		Do not use over large areas of the body, particularly over raw surfaces or blistered areas		When using this product avoid contact with the eyes		Stop use and ask a doctor if - condition worsens		- symptoms last more than 7 days		- condition clears up and occurs again within a few days		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Directions		- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily		- children under 2 years of age: ask a doctor		Other information store at room temperature		Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine		Questions or comments? 1-800-430-5490	
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Mfg. for: Honeywell Safety Products USA, Inc. Smithfield, RI 02917 032204 Rev. H





032204 Rev. H North Burn Relief Spray
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032204K Rev. F (Page 3 of 3)



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-0201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
OCTOXYNOL-9 (UNII: 7JPC6Y25Q5)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TROLAMINE (UNII: 9O3K93S3TK)	
TEA TREE OIL (UNII: VIF565UC2G)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0201-10	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/18/2017	09/18/2018
2	NDC:0498-0201-59	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/15/2013	09/18/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/15/2013	09/18/2018

BURN RELIEF

lidocaine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-0221
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Route of Administration TOPICAL

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TEA TREE OIL (UNII: VIF565UC2G)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0221-10	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/18/2018	
2	NDC:0498-0221-59	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Labeler - Honeywell Safety Products USA, Inc (118768815)

Registrant - Honeywell Safety Products USA, Inc (118768815)