

BURN MIST- lidocaine hydrochloride spray
Water-Jel Technologies

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.

Burn Spray

Active ingredient

Lidocaine HCl 2%

Purpose

External analgesic

Uses

for the temporary relief of pain associated with minor burns

Warnings

For external use only

Do not use

in large quantities, particularly over raw surfaces or blistered areas

When using this product

avoid contact with eyes

- 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.

- 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: consult a doctor

Other information

store at room temperature

you may report a serious adverse reaction to this product to 1-800-275-3433

Inactive ingredients

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

Questions or comments?

1-800-275-3433 info@waterjel.com www.waterjel.com
 Manufactured by Water-Jel Technologies, Inc., 50 Broad Street,
 Carlstadt, NJ 07072, USA

Principal Display Panel

Drug Facts
Active ingredient Lidocaine HCL 2% **Purpose** External analgesic
Uses for the temporary relief of pain associated with minor burns
Warnings
For external use only
Do not use in large quantities, 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 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: consult a doctor
Other information
 ■ store at room temperature ■ you may report a serious adverse reaction to this product to 1-800-275-3433
Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, tea tree oil, tetramine water
Questions or comments? 1-800-275-3433 info@waterjel.com www.waterjel.com
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WATERJEL
Burn Spray
External Analgesic
Relieves Burn Pain Fast
 Lidocaine HCL 2%
 • For minor scalds and burns
 • Cools and soothes
 • Water soluble non-aerosol spray
 • Quick pain relief
 Manufactured by Water-Jel Technologies Inc.
 50 Broad Street, Carlstadt, NJ 07072
2 Fl. Oz. (59 mL)

BURN MIST

lidocaine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98P200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2208 (100000 MPAS) (UNII: VM7F0B23ZI)	
TROLAMINE (UNII: 9O3K93S3TK)	

TEA TREE OIL (UNII: VIF565UC2G)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

METHYLPARABEN (UNII: A2I8C7H9T)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-201-10	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/17/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/17/2010	

Labeler - Water-Jel Technologies (155522589)

Registrant - Water-Jel Technologies (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-201)

Revised: 12/2020

Water-Jel Technologies