

BURN JEL- lidocaine hydrochloride gel

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 Jel

Active ingredient

Lidocaine HCl 2.0 %

Purpose

External analgesic

Uses

for the temporary relief of pain associated with minor burns

Warnings

For external use only

Do not use

- on large areas of the body
- on broken, blistered or oozing skin

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- conditions 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
- spread a thick even layer over affected skin
- 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 800-275-3433

Inactive ingredients

acrylates/C10-30 alkyl acrylate, carbomer, diazolidinyl urea, disodium EDTA, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, triethanolamine, 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 (continued)

Stop use and ask a doctor if

■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again in 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 3-4 times daily ■ spread a thick, even layer over affected skin ■ children under 2 years: consult a doctor.

Other information

■ store at room temperature ■ do not use packet if opened or torn

Inactive ingredients

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Manufactured by Water-Jel Technologies, Inc.
50 Broad St., Carlstadt, NJ 07072 USA 08/20

QUIET ZONE

To open fold along dotted line
and tear at notch



WATERJEL[®] BURNJEL[®] EXTERNAL ANALGESIC



CONTAINS
PAIN RELIEVING
LIDOCAINE HCL 2%

Active Ingredient: Lidocaine HCL 2%

- For Fast Relief of Minor Burns
- Cools and Soothes

Drug Facts

Uses for the temporary relief of pain associated with minor burns

Warnings For external use only

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■ on broken, blistered or oozing skin

When using this product

■ avoid contact with the eyes ▶

net wt. 3.5g (1/8 oz.)



burn  jel
EXTERNAL ANALGESIC

Contains Pain Relieving
Lidocaine 2% HCl

FOR FAST RELIEF OF MINOR BURNS

► Fast Pain Relief ► Cools & Soothes

2 fl oz. (59ml)

Drug Facts

Active ingredient

Lidocaine 2% HCl

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External analgesic

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Water-Jel Technologies, Inc.,
50 Broad Street, Carlstadt,
NJ 07072, USA

REV D

20200526_WJ_US_BJ_2oz_rev0



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WATER-JEL®

burn  **jel**
EXTERNAL ANALGESIC

Contains Pain Relieving
Lidocaine 2% HCl

**FOR FAST RELIEF
OF MINOR BURNS**

- ▶ Fast Pain Relief
- ▶ Cools & Soothes

4 fl oz. (118ml)

Drug Facts

Active Ingredient

Lidocaine 2% HCl

Purpose

External analgesic

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REV 0

20200526_WJ_US_BJ_4oz_rev0



BURN JEL

lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
CARBOMER HOMOPOLYMER TYPE B (UNII: HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-200-13	24 in 1 CARTON	04/17/2010	
1	NDC:59898-200-12	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59898-200-16	6 in 1 BOX	04/17/2010	
2		3.5 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:59898-200-11	24 in 1 CARTON	04/17/2010	
3	NDC:59898-200-10	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:59898-200-17	1728 in 1 CARTON	04/17/2010	
4		3.5 mL in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:59898-200-35	3.5 mL in 1 PACKET; Type 0: Not a Combination Product	04/17/2010	
6	NDC:59898-200-15	25 in 1 BOX	04/17/2010	
6		3.5 mL in 1 PACKET; Type 0: Not a Combination Product		
7	NDC:59898-200-49	10 in 1 KIT	04/17/2010	
7		3.5 mL in 1 PACKET; Type 0: Not a Combination Product		

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/17/2010	

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Labeler - Water-Jel Technologies (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-200)

