

BURN JEL- lidocaine hydrochloride gel

Water-Jel Technologies

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

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www.waterjel.com

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

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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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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

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Questions or comments?

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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 Drug | M017 | 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) |

