

**EBSL-5- lidocaine hydrochloride**  
**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.*

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**EBSL-5**

**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
- symptoms clears 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 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
- do not use packeeet if opened or torn
- you may report a serious adverse reaction to this product to 800-275-3433

**Inactive ingredients**

triethanolamine, mealeuca alternifolia (tea tree) leaf oil, glycerin, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, carbomer, octoxynol-9, acrylates C/10-30 alkyl acrylate, disodium EDTA

**Questions**

1-800-275-3433 [www.waterjel.com](http://www.waterjel.com)

**MEDICAL DEVICES**

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- 2 4" x 4" Burn Dressing
  - 2 4" x 16" Burn Dressing
  - 1 8" x 18" Burn Dressing
  - 1 12" x 16" Face Mask
  - 2 3" Rolls of Gauze
  - 1 Pair of Scissors
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**Principal Display Panel**

# EMERGENCY BURN STATION



- Stops the burning process
- Cools the burn and relieves pain
- Helps prevent contamination
- Non-adherent dressing

**WATER-JEL**  
Cools the Burn - Relieves the Pain!

ITEM # 0618

## WATER-JEL<sup>®</sup> BURN DRESSING STERILE GEL-SOAKED



**EMERGENCY FIRST AID FOR BURNS**  
CONTENTS: ONE 8" X 18" DRESSING (20 cm x 45 cm)



ITEM # 0618

### WATER-JEL<sup>®</sup> BURN DRESSING STERILE GEL-SOAKED

**WATER-JEL**  
Cools the Burn - Relieves the Pain!

- Stops the burning process
- Cools the burn and relieves pain
- Helps prevent contamination
- Non-adherent dressing

**EMERGENCY FIRST AID FOR BURNS**  
CONTENTS: ONE 4" X 10" DRESSING (10 cm x 25 cm)

ITEM # 0618

### WATER-JEL<sup>®</sup> BURN DRESSING STERILE GEL-SOAKED

**WATER-JEL**  
Cools the Burn - Relieves the Pain!

- Stops the burning process
- Cools the burn and relieves pain
- Helps prevent contamination
- Non-adherent dressing

**EMERGENCY FIRST AID FOR BURNS**  
CONTENTS: ONE 4" X 6" DRESSING (10 cm x 15 cm)

To open fold along dotted line and tear at notch

**WATER-JEL**  
**BURN JEL**<sup>®</sup>  
 EXTERNAL ANALGESIC

**CONTAINS**  
 PAIN RELIEVING  
 LIDOCAINE 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  
 Do not use ■ on large areas of the body ■ on broken, blistered or oozing skin  
**When using this product** ■ avoid contact with the eyes

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

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

**Questions?** 1-800-275-3433  
 www.waterjel.com

WATER-JEL TECHNOLOGIES, LLC  
 Carlstadt, NJ 07072 USA REV 05

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**WATERJEL®**  
**BURNJEL®**  
EXTERNAL ANALGESIC

 **CONTAINS  
PAIN RELIEVING  
LIDOCAINE 2%**

**FOR FAST RELIEF  
OF MINOR BURNS**

- Fast Pain Relief
- Cools & Soothes

4 fl oz. (118mL)

**Drug Facts**

Active ingredient	Purpose
Lidocaine HCl 2%	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 the eyes

**Stop use and ask a doctor if**

- condition worsens
- symptoms persist for more than 7 days
- symptoms clear up and occur 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 3-4 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 ■ you may report a serious adverse reaction to this product to 1-800-275-3433

**Inactive ingredients** Water, Triethanolamine, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Glycerin, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben, Carbomer, Octoxynol-9, Acrylates/C10-30 Alkyl Acrylate, Disodium EDTA

**Questions or comments?**

1-800-275-3433 • info@waterjel.com • www.waterjel.com  
WATER-JEL Technologies, Carlstadt, NJ 07072 USA REV 06



lidocaine hydrochloride kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59898-140
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-140-40	1 in 1 KIT; Type 0: Not a Combination Product	06/11/2014	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 PACKET	35 mL
Part 2	1 BOTTLE, PLASTIC	59 mL

## Part 1 of 2

### BURN JEL

lidocaine hydrochloride gel

### Product Information

<b>Item Code (Source)</b>	NDC:59898-200
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<b>Route of Administration</b>	TOPICAL
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### 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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
CARBOMER HOMOPOLYMER TYPE B (UNII: HHT01ZNK31)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-200-49	10 in 1 BOX		
1	NDC:59898-200-35	3.5 mL in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/11/2014	

## Part 2 of 2

### BURN JEL

lidocaine hydrochloride gel

## Product Information

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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
CARBOMER HOMOPOLYMER TYPE B (UNII: HHT01ZNK31)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-200-10	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/11/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/11/2014	

**Labeler** - Water-Jel Technologies (155522589)

### Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-140)

Revised: 12/2017

Water-Jel Technologies