

**FSK-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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**FSK-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 2" x 6" Burn Dressings
  - 2 4" x 4" Burn Dressings
  - 1 12" x 16" Face Mask
  - 1 2" x 2.2 yd Elastic Bandage
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## Principal Display Panel



## Principal Display Panel Packet

To open fold along dotted line  
and tear at notch

**WATER-JEL®**  
**BURN JEL®**  
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 C/10-30 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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lidocaine hydrochloride kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59898-170
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-170-43	1 in 1 KIT	06/11/2014	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	25 PACKET	87.5 mL

### Part 1 of 1

### 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 HOMO POLYMER 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 HOMO POLYMER 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:59898-200-15	25 in 1 CARTON		
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	

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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(59898-170)

Revised: 12/2017

Water-Jel Technologies