

IWK-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.

IWK-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

MEDICAL DEVICES

- 1 12" X 16" Face Mask
 - 1 8" x 18" Burn Dressing
 - 2 4" x 4" Burn Dressings
 - 1 4" x 16" Burn Dressing
 - 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-180
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-180-44	1 in 1 KIT	06/12/2014	

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

Item Code (Source)	NDC:59898-200
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Route of Administration	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	06/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/12/2014	

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

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-180)

Revised: 12/2017

Water-Jel Technologies