

BURN JEL PLUS- gel for burns 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 Plus

Active ingredient

Lidocaine HCl 2.5%

Purpose

External analgesic

Uses

for the temporary relief of pain associated with minor burns

Warnings

For external use only

Do not use

in large quantities, particularly over raw surfaces or blistered areas

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 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
- children under 2 years of age: consult a doctor

Inactive ingredients

carbomer 940, carbomer 1342, diazolidinyl urea, edetate disodium, glycerin, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine, vitamin E acetate

Questions ?

1-800-275-3433 www.waterjel.com

Principal Display Panel



Drug Facts

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REV 6

BURN JEL PLUS

gel for burns gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.5 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 COPOLYMER TYPE B (UNII: 1G56KV7BUJ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-202-10	1 in 1 CARTON	04/10/2010	
1		59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59898-202-11	24 in 1 CARTON	04/10/2010	
2		59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59898-202-12	1 in 1 CARTON	04/10/2010	
3		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:59898-202-13	24 in 1 CARTON	04/10/2010	
4		118 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	04/10/2010	

Labeler - Water-Jel Technologies (155522589)

Registrant - Water-Jel Technologies (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-202)

Revised: 12/2017

Water-Jel Technologies