

UNBURN- lidocaine hydrochloride 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.

Water-Jel Unburn

Active ingredient

Lidocaine HCl 2.5%

Purpose

External analgesic

Uses

for the temporary relief of pain associated with:

- sunburn
- minor burns
- minor skin irritations
- insect bites

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

- condition 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
- children under 2 years of age: consult a doctor

Other information

- store at 15 ° to 25 °C (59 ° to 77 °F)
- do not freeze
- you may report a serious adverse reaction to this product to 1-800-275-3433

Inactive ingredients

acrylates/C20-30 alkyl acrylate crosspolymer, aloe, carbomer, diazolidnyl urea, edetate disodium, glyceryl-7 stearate, methylparaben, octoxynol-9, polysorbate 20, propylene glycol, propylparaben, purified water, spearmint oil, tea tree oil, trolamine, vitamin E acetate

1-800-275-3433

Monday - Friday (9a.m. - 5 p.m. EST)

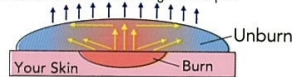
www.unburn.info

Principle Display Panel



REDUCES BURN PROGRESSION

- Controlled cooling by acting as a heat exchanger
- Promotes heat transfer
- As burn temperature drops, convection decreases heat until the burned area and gel are equal



Drug Facts	
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Questions? 1-800-275-3433 Monday - Friday (8 a.m. - 5 p.m. EST) www.unburn.info	

WATER-JEL Technologies, Carlstadt, NJ 07072 USA Rev. 0



SCAN HERE FOR MORE INFORMATION OR VISIT www.unburn.info



lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-500
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
METHYL PARABEN (UNII: A2I8C7HI9T)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SPEARMINT OIL (UNII: C3M81465G5)	
TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-500-10	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/17/2013	
2	NDC:59898-500-14	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/17/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/17/2013	

Labeler - Water-Jel Technologies (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-500)

