ANALGESIC- lidocaine hydrochloride gel
Welly Health PBC

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.

Drug Facts

Active ingredient

Lidocaine

HCl 2.0%

Purpose

Topical

pain relief

Uses

Temporary pain relief for minor burns

Warnings

External use only. Keep out of reach of children.

Do not use

- near eyes, if this happens, rinse thoroughly with water
- in large quantities, particularly over raw or blistered areas

Stop use, ask a doctor

- if conditions worsen or last more than 7 days or clears up and returns. If ingested contact a Poison Control Center directly

Directions

- adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily
- children under 2: do not use, ask a doctor

Inactive ingredients

aloe vera, carbomer, germaben II, menthol, propylene glycol, purified water, triethanolamine, vitamin E acetate

Welly Health PBC, Minn., MN 55402

1-833-BE-WELLY

Principal Display Panel - Welly Health Burn Gel Pouch Label

Welly™

Burn Gel

0.9/ 1/32 OZ

BURN GEL

welly

Burn Gel

0.9g / 1/32 OZ

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BURN GEL

Drug Facts (continued)

Warnings (continued)

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ANALGESIC

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72663-500
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 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
aloe vera leaf (UNII: ZY81Z83H0X)	
carboxypolymethylene (UNII: 0A5MM307FC)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	

menthol, unspecified form (UNII: L7T10EIP3A)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
trolamine (UNII: 9O3K93S3TK)	
.alpha.-tocopherol, d- (UNII: N9PR3490H9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-500-04	0.9 mL in 1 POUCH; Type 0: Not a Combination Product	02/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/25/2019	

Labeler - Welly Health PBC (116766884)

Revised: 2/2019 Welly Health PBC