FIRST AID ONLY BURN- lidocaine hydrochloride gel
Acme United Corporation

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.

First Aid Only Burn Gel

• ACTIVE INGREDIENT

Lidocaine Hydrochloride 2%

• PURPOSE

External Analgesic

USES

Temporarily relieves pain associated with minor burns

WARNINGS

For external use only.

Avoid contact with eyes

Do not use

▪ in large quantities, particularly over raw surfaces or blistered areas

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 reach of children.

. If swallowed get medical help or contact Poison Control immediately

DIRECTIONS

Adults and children 2 years and over:

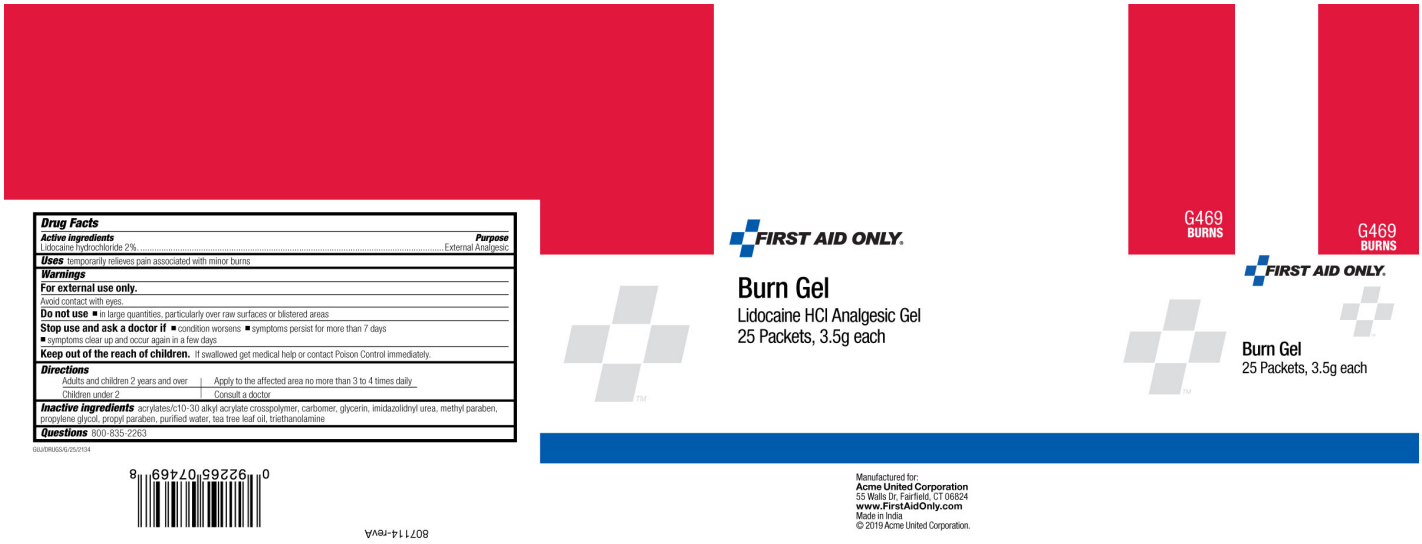
Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: consult a doctor

INACTIVE INGREDIENTS

Acrylates/C10-30 alkyl acrylate crosspolymer, Carbomer, Glycerin, Imidazolidinyl urea, Methylparaben, Propylparaben, Propylene Glycol, Purified water, Tea Tree Leaf Oil, Triethanolamine.

QUESTIONS 800-835-2263



FIRST AID ONLY BURN

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-5010(NDC:50382-020)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
TEA TREE OIL (UNII: VIF565UC2G)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
IMIDUREA (UNII: M629807ATL)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0924-5010-01	6 in 1 CARTON	01/02/2020	
1		3.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0924-5010-02	25 in 1 CARTON	01/02/2020	

2		3.5 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0924-5010-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product	01/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/02/2020	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5010) , repack(0924-5010)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5010) , repack(0924-5010)

Revised: 12/2019 Acme United Corporation