REDICARE BURN GEL- redicare burn gel gel Redicare LLC

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 Gel USA

Active Ingredient

Lidocaine HCl 2.0%

Purpose

Topical pain relief

Uses

Temporary pain relief for minor burns

Warnings

For external use only

Do not use

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

Stop use and ask doctor

if condition worsens or persists for more than 7 days or 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

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

Inactive Ingredients

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

REDICARE

BURN GEL

for minor burns, scalds & sunburn

WITH ALOE VERA FOR BEST RELIEF

3.5g / 1/8 oz.

NDC 71105-500-01

DRUG FACTS...



Drug Facts (continued)

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Made in USA for Redicare LLC - 866.561.5650 redicare burn gel gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71105-500	
Route of Administration	TOPICAL			

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

Inactive Ingredients		
Ingredient Name	Strength	
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)		
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
MENTHOL (UNII: L7T10EIP3A)		
ALPHA-TO CO PHEROL ACETATE (UNII: 9E8X80D2L0)		
TROLAMINE (UNII: 9O3K93S3TK)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		

ı	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:71105-500-02	15 in 1 BOX	10/09/2019		
l	1 NDC:71105-500-01	3.3 g 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 final	part346	10/09/2019		

Labeler - Redicare LLC (800149346)

Revised: 10/2019 Redicare LLC