XEROBURN BURN GEL- lidocaine hydrochloride gel
Dynarex 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.

1290 XeroBurn Burn Gel 67777-129-00
1291 XeroBurn Burn Gel 67777-129-01
1292 XeroBurn Burn Gel 67777-129-02

Active Ingredient

Lidocaine Hydrochloride 2%

Purpose

Analgesic

Use(s)

■ For the temporary relief of pain associated with ■ Minor burns ■ Sunburn

■ Provides cooling pain relief

Warnings

For External Use Only

Do not use

■ On wounds or damaged skin

■ In large quantities, particularly over raw surfaces or blistered areas

When using this product

■ Avoid contact with the eyes

■ Do not bandage tightly

Stop use and ask a doctor if

■ Condition worsens

■ Symptoms persist for more than 7 days

■ Symptoms clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

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 room temperature 15º-30ºC (59º-86ºF)

• Tamper Evident. Do not use if seal is damaged.

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosscopolymer, Carbomer, Glycerin, Imidazolidinyl Urea, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Tea Tree Leaf Oil, Triethanolamine

Questions?

1-888-396-2739 Monday - Friday, 9AM - 5PM EST

Label

XEROBURN BURN GEL
lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-129
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 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
IMIDUREA (UNII: M629807ATL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TEA TREE OIL (UNII: VIF565UC2G)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-129-10	600 in 1 CASE	09/07/2017	
1	NDC:67777-129-01	6 in 1 BOX		
1		3.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67777-129-09	600 in 1 CASE	09/07/2017	
2	NDC:67777-129-00	25 in 1 BOX		
2		3.5 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:67777-129-02	1728 in 1 CASE	09/07/2017	
3		3.5 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 not final	part348	09/07/2017	

Labeler - Dynarex Corporation (008124539)

Revised: 1/2023 Dynarex Corporation