

BURN EASE- burn ease gel
ProStat First Aid 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.

3832 Burn Ease

Active Ingredient

Lidocaine Hydrochloride 2%

Purpose

Analgesic

Use(s)

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

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.

Route of Administration	TOPICAL
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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)	
IMIDUREA (UNII: M629807ATL)	
TROLAMINE (UNII: 903K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TEA TREE OIL (UNII: VIF565UC2G)	

Product Characteristics

Color		Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-3832-2	600 in 1 CASE	04/10/2023	
1	NDC:58228-3832-1	6 in 1 BOX		
1		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	04/10/2023	

