

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.

3831 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.

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

Inactive Ingredients

Acrylates/C10-30 alkyl acrylate crosspolymer, Carbomer, Glycerin, Imidazolidinyl urea, Methyparaben, Propylene glycol, Propylparaben, Purified water, Tea tree leaf oil, Triethanolamine

Questions?

1-888-900-2920 8AM - 4PM PST

Label



3831 Burn Ease

BURN EASE

burn ease gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-3831
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (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)	
GLYCERIN (UNII: PDC6A3C0OX)	

TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
IMIDUREA (UNII: M629807ATL)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

Product Characteristics

Color		Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-3831-2	480 in 1 CASE	04/10/2023	
1	NDC:58228-3831-1	20 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	

Labeler - ProStat First Aid LLC (061263699)