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.

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, Methylparaben, Proplyene glycol, Propylparaben, Purified water, Tea tree leaf oil, Triethanolamine

Questions?

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

Label



Burn Ease

BURN EASE							
burn ease gel							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-3832				

Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingredie	ent Name		Basis of Strength		
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - JNII:98PI200987)		IE -	LIDOCAINE HYDROCHLORIDE ANHYDROUS		
Inactive Ingredients					
Ingredient Name					
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)					
IMIDUREA (UNII: M629807ATL)					
TROLAMINE (UNII: 903K93S3TK)					
GLYCERIN (UNII: PDC6A3C0OX)					
METHYLPARABEN (UNII: A2I8C7H	II9T)				
PROPYLPARABEN (UNII: Z8IX2SC10H)					
WATER (UNII: 059QF0KO0R)					
CARBOMER HOMOPOLYMER TY 4Q93RCW27E)	PE C (ALLYL PENTAERYTH		ROSSLINKED) (UNII:		
PROPYLENE GLYCOL (UNII: 6DC	9Q167V3)				
TEA TREE OIL (UNII: VIF565UC2G)				
Product Characteristics					
Color		Score			
Shape F	REEFORM	Size			
Flavor		Imprin	t Code		
Contains					

Strength

Strength

2 g in 100 g

Packaging

#	ltem 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		
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Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpart34804/10/2023

Revised: 3/2023

ProStat First Aid LLC