BURNAID BURN GEL- tea tree oil gel Clear Healthcare LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Burnaid® Burn Gel

Drug Facts

Active ingredient

Meleleuca Oil 10mg/g

Purpose

For the first aid treatment of minor burns, scalds and sunburn.

Warning

- Do not use on serious burns.
- FOR EXTERNAL USE ONLY.
- Discontinue use if irritation occurs.
- Do not store at extreme temperatures.
- Keep out of reach of children. If
- swallowed, get medical help or contact a Poison Control Center right away.

Inactive ingredients

Purified Water, Propylene Glycol, PEG 7 Glyceryl Cocoate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Tocopheryl Acetate, Lactic Acid, Parabens

Directions









- 1. Tear open sachet. **2.** Apply gel liberally to affected area. Do not rub in. **3.** Cover if necessary.
- **4.** Seek medical attention if pain persists.

PRINCIPAL DISPLAY PANEL - 3.5 g Packet Label

NDC 51121-035-12

Burnaid® BURN GEL

For first aid use on minor burns, scalds and sunburn

- Cools
- Soothes

1/8 OZ. (3.5g)

SINGLE USE ONLY. DISCARD AFTER USE. IF PACK HAS BEEN DAMAGED DO NOT USE.

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Inactive ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Lactic Acid, PEG 7 Glyceryl Cocoate, Propylene Glycol, Purified Water, Tocopheryl Acetate, Triethanolamine, Parabens.

Directions:









1. Tear open sachet. 2. Apply gel liberally to affected area. Do not rub in, 3, Cover if necessary. Seek medical attention if pain persists.

Manufactured for Clear Healthcare LLC Lomita, CA 90717 Distributed by DUKAL Corporation 2 Fleetwood Court, Ronkonkoma, NY 11779 Phone: (631) 656-3800 www.dukal.com BS-35 www.burnaid.com



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BURNAID BURN GEL

tea tree oil gel

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:51121-035
Route of Administration	TOPICAL	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Tea Tree Oil (Tea Tree Oil)	Tea Tree Oil	10 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
Water			
Propylene Glycol			
PEG-7 Glyceryl Cocoate			
Trolamine			
.AlphaTocopherol Acetate			
Lactic Acid			

I	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:51121-035-12	3.5 g in 1 PACKET				
2	NDC:51121-035-04	115 g in 1 BOTTLE, PLASTIC				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Unapproved drug other		11/0 4/20 13		

Labeler - Clear Healthcare LLC (078886273)

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