DERMOPLAST SUNBURN AND BURN RELIEF- benzocaine and levomenthol spray Advantice Health, 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.

Dermoplast® Sunburn & Burn Relief

Drug Facts

Active ingredients	Purpose
Benzocaine 20%	Topical analgesic
Menthol 0.5%	Topical analgesic

Uses

for temporary relief of pain and itching associated with

- sunburn
- insect bites
- minor cuts
- scrapes
- minor burns
- minor skin irritations

Warnings

For external use only

Flammable do not use near heat, flame, or fire or while smoking

Allergy alert

Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

When using this product

- avoid contact with eyes. Do not spray in the face or mouth.
- use only as directed
- intentional misuse by deliberately concentrating or inhaling the contents can be harmful or fatal
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

itching, rash or irritation develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center 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

- to use this product, hold the can 6 to 12 inches away from the affected area. Direct spray nozzle towards skin and press button to activate spray.
- to apply to face, spray in palm of hand and gently apply

Other information

- avoid contact with leather, fabric and upholstery to prevent possible staining or discoloration
- store at 20-25°C (68-77°F)

Inactive ingredients

acetylated lanolin alcohol, aloe vera gel (decolorized), butane, cetyl acetate, hydrofluorocarbon 152a, methylparaben, PEG-400 monolaurate, polysorbate 85

Questions?

1-800-345-0032 Mon - Fri 8AM- 5PM EST **Dermoplast.com**

Distributed by Advantice Health, LLC Cedar Knolls, NJ 07927

PRINCIPAL DISPLAY PANEL - 78 g Can Label

Dermoplast®
Pain Relieving Spray
HOSPITAL TRUSTED BRAND
SUNBURN &
BURN RELIEF
RELIEVES PAIN & ITCH

from sunburns, minor burns

& other skin irritations

#1 Doctor Recommended Brand*

Provides Fast Pain Relief

Menthol Cools & Comforts

Soothing Aloe & Lanolin

NET WT. 2.75 oz (78 g)



DERMOPLAST SUNBURN AND BURN RELIEF

benzocaine and levomenthol spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16864-681
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	5 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
PEG-8 LAURATE (UNII: 76208IWA10)			
POLYSORBATE 85 (UNII: A7F3N56197)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)			
CETYL ACETATE (UNII: 4Q43814HXS)			
BUTANE (UNII: 6LV4FOR43R)			
1,1-DIFLUOROETHANE (UNII: 0B1U8K2ME0)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:16864-681- 01	78 g in 1 CAN; Type 0: Not a Combination Product	05/15/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	05/15/2021	

Labeler - Advantice Health, LLC (192527062)

Revised: 5/2021 Advantice Health, LLC