

DERMOPLAST PAIN RELIEVING- 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® Pain Relieving

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 STRENGTH

**PAIN, BURN
& ITCH**

RELIEVES PAIN FROM:

Minor Cuts & Scrapes, Burns,
Sunburns and Bug Bites

Fast Itch & Burn Relief

Provides Fast
Pain Relief

Cools and
Comforts

Soothing Aloe
& Lanolin

NET WT. 2.75 oz (78 g)

<p>Drug Facts (continued)</p> <p>Directions</p> <table border="1"> <tr> <td>Adults and children 2 years of age and older</td> <td>apply to affected area not more than 3 to 4 times daily</td> </tr> <tr> <td>Children under 2 years of age</td> <td>consult a doctor</td> </tr> </table> <ul style="list-style-type: none"> 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 <p>Other information ■ avoid contact with leather, fabric and upholstery to prevent possible staining or discoloration ■ store at 20-25°C (68-77°F)</p> <p>Inactive ingredients acetylated lanolin alcohol, aloe vera gel (decolorized), butane, cetyl acetate, hydrofluorocarbon 152a, methylparaben, PEG-400 monolaurate, polysorbate 85</p> <p>Questions? 1-800-345-0032 Mon - Fri 8AM- 5PM EST Dermoplast.com</p>	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	 <p>Dermoplast[®] Pain Relieving Spray</p> <p>HOSPITAL STRENGTH</p> <p>PAIN, BURN & ITCH</p> <p>RELIEVES PAIN FROM: Minor Cuts & Scrapes, Burns, Sunburns and Bug Bites</p> <p>Fast Itch & Burn Relief</p> <ul style="list-style-type: none"> Provides Fast Pain Relief Cools and Comforts Soothing Aloe & Lanolin <p>NET WT. 2.75 oz (78 g)</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Benzocaine 20%</td> <td>Topical analgesic</td> </tr> <tr> <td>Menthol 0.5%</td> <td>Topical analgesic</td> </tr> </tbody> </table> <p>Uses for temporary relief of pain and itching associated with</p> <ul style="list-style-type: none"> ■ sunburn ■ insect bites ■ minor cuts ■ scrapes ■ minor burns ■ minor skin irritations <p>Warnings For external use only</p> <p>Flammable do not use near heat, flame, or fire or while smoking</p> <p>Allergy alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, buta caine, benzocaine or other "caine" anesthetics.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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 <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active ingredients	Purpose	Benzocaine 20%	Topical analgesic	Menthol 0.5%	Topical analgesic
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DERMOPLAST PAIN RELIEVING

benzocaine and levomenthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16864-680
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: 762O8IWA10)				
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
1	NDC:16864-680-01	78 g in 1 CAN; Type 0: Not a Combination Product	01/01/2014	
2	NDC:16864-680-02	56 g in 1 CAN; Type 0: Not a Combination Product	01/01/2014	
3	NDC:16864-680-03	85 g in 1 CAN; Type 0: Not a Combination Product	01/01/2014	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL		part348	01/01/2014	

Labeler - Advantice Health, LLC (192527062)

Revised: 3/2021

Advantice Health, LLC