DERMOPLAST PAIN RELIEVING- benzocaine and levomenthol spray
Moberg Pharma North America 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.

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Dermoplast® Pain Relieving

Drug Facts

<table>
<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>

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 apply to affected area not more
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 Moberg Pharma North America LLC Cedar Knolls, NJ 07927

PRINCIPAL DISPLAY PANEL - 78 g Can Label

HOSPITAL TRUSTED
Dermoplast®
Anesthetic
PAIN & ITCH SPRAY
Fast Relief
Cools & Comforts
No Touch Application
Contains
Aloe &
Lanolin

SAFE FOR CHILDREN 2 YEARS AND OLDER
NET WT
2.75 oz (78 g)
**DERMOPLAST PAIN RELIEVING**
benzocaine and levomenthol spray

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:</th>
<th>16864-680</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOPICAL</td>
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<td></td>
<td></td>
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</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZOCAINE</td>
<td>BENZOCAINE</td>
<td>200 mg in 1 g</td>
</tr>
<tr>
<td>LEVOMENTHOL</td>
<td>LEVOMENTHOL</td>
<td>5 mg in 1 g</td>
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</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEG-8 LAURATE</td>
<td></td>
</tr>
<tr>
<td>POLYSORBATE 85</td>
<td></td>
</tr>
<tr>
<td>METHYLPARABEN</td>
<td></td>
</tr>
<tr>
<td>ALOE VERA LEAF</td>
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</tr>
<tr>
<td>ACETYLATED LANOLIN ALCOHOLS</td>
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<tr>
<td>CETYL ACETATE</td>
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</tr>
<tr>
<td>BUTANE</td>
<td></td>
</tr>
<tr>
<td>1,1-DIFLUOROETHANE</td>
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### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
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<td>NDC:16864-680-01</td>
<td>78 g in 1 CAN; Type 0: Not a Combination Product</td>
<td>01/01/2014</td>
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<td>NDC:16864-680-02</td>
<td>56 g in 1 CAN; Type 0: Not a Combination Product</td>
<td>01/01/2014</td>
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### Marketing Information

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<thead>
<tr>
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<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>OTC MONOGRAPH NOT FINAL</td>
<td>part348</td>
<td>01/01/2014</td>
<td></td>
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**Labeler** - Moberg Pharma North America LLC (192527062)

Revised: 11/2018  
Moberg Pharma North America LLC