

PAIN, BURN, AND ITCH RELIEF- benzocaine 20%, menthol 0.5% spray
Derma Care Research Labs, 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.

DCH Pain, Burn, Itch Spray

Benzocaine 20%, Menthol 0.5%

Topical Analgesic

For the temporary relief of pain and itching associated with sunburn, minor skin irritations, insect bites, scrapes, minor cuts, and minor burns.

For external use only. Flammable--Keep away from fire or flame. **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. Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120F. **Stop use and ask a doctor if** condition worsens, if symptoms persist for more than 7 days or clear up and occur again within a few days, itching, rash or irritation develops.

If swallowed, get medical help or contact a Poison Control Center right away.

Adults and children 2 years of age and older, apply to the affected area not more than 3 to 4 times daily. Children under 2 years of age: ask 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 the button to activate the spray. To apply to face, spray into palm of hand and gently apply.

Acetylated Lanolin Alcohol, Alcohol Denat., Aloe Barbadosensis Leaf Extract, Cetyl Acetate, Helianthus Annuus (Sunflower) Seed Oil, PEG-8 Laurate, Polysorbate 85.



DCH LABS

Drug Facts

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

Uses For the temporary relief of pain and itching associated with

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

Warnings

Flammable - Keep away from fire or flame.

For external use only.

When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water • avoid contact with broken skin

- contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F

Stop use and ask a doctor if • condition worsens • rash or irritation develops and lasts for more than 7 days or clear up and occur again within a few days

Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • adults and children 12 years or older: apply to affected area not more than 3 to 4 times daily • children under 12 years of age: ask a doctor • to apply to face, spray into palm of hand and gently apply

Inactive ingredients

acetylated lanolin alcohol, alcohol denat., aloe barbadensis leaf extract, cetyl acetate, helianthus annuus (sunflower) seed oil, PEG-8 laurate, polysorbate 85

*This product is not manufactured or distributed by Moberg Pharma AB, owner of the registered trademark Dermoplast®



Manufactured by:
DermaCare Research Labs, LLC
440 Fentress Blvd., Daytona Beach, FL 32114



Pain, Burn & Itch Relief Spray

Hospital Strength

Benzocaine 20%
Menthol 0.5%

For Immediate Relief
from Minor Cuts & Scrapes,
Burns, Sunburns and Bug Bites

• Cools & Comforts

• Sprays at Any Angle

* Compare to active ingredients in Dermoplast®

NET WT 3 OZ (85 g)

PAIN, BURN, AND ITCH RELIEF

benzocaine 20%, menthol 0.5% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-343
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)	
ALCOHOL (UNII: 3K9958V90M)	

CETYL ACETATE (UNII: 4Q43814HXS)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
PEG-8 LAURATE (UNII: 76208IWA10)	
POLYSORBATE 85 (UNII: A7F3N56197)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-343-03	85 g in 1 CAN; Type 0: Not a Combination Product	01/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/30/2023	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(72839-343)

Revised: 6/2023

Derma Care Research Labs, LLC