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. **Allergyalert**: 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 Barbadensis Leaf Extract, Cetyl Acetate, Helianthus Annuus (Sunflower) Seed Oil, PEG-8 Laurate, Polysorbate 85.

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: 762O8IWA10)	
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