OUTBACK PAIN RELIEF- camphor 6%, menthol 16% cream
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.

Outback Pain Relief Liquid Cream

Camphor 6%, Menthol 16%

Topical Analgesic

For the temporary relief of minor aches and pain associated with simple backaches, arthritis, strains, bruises, and sprains.

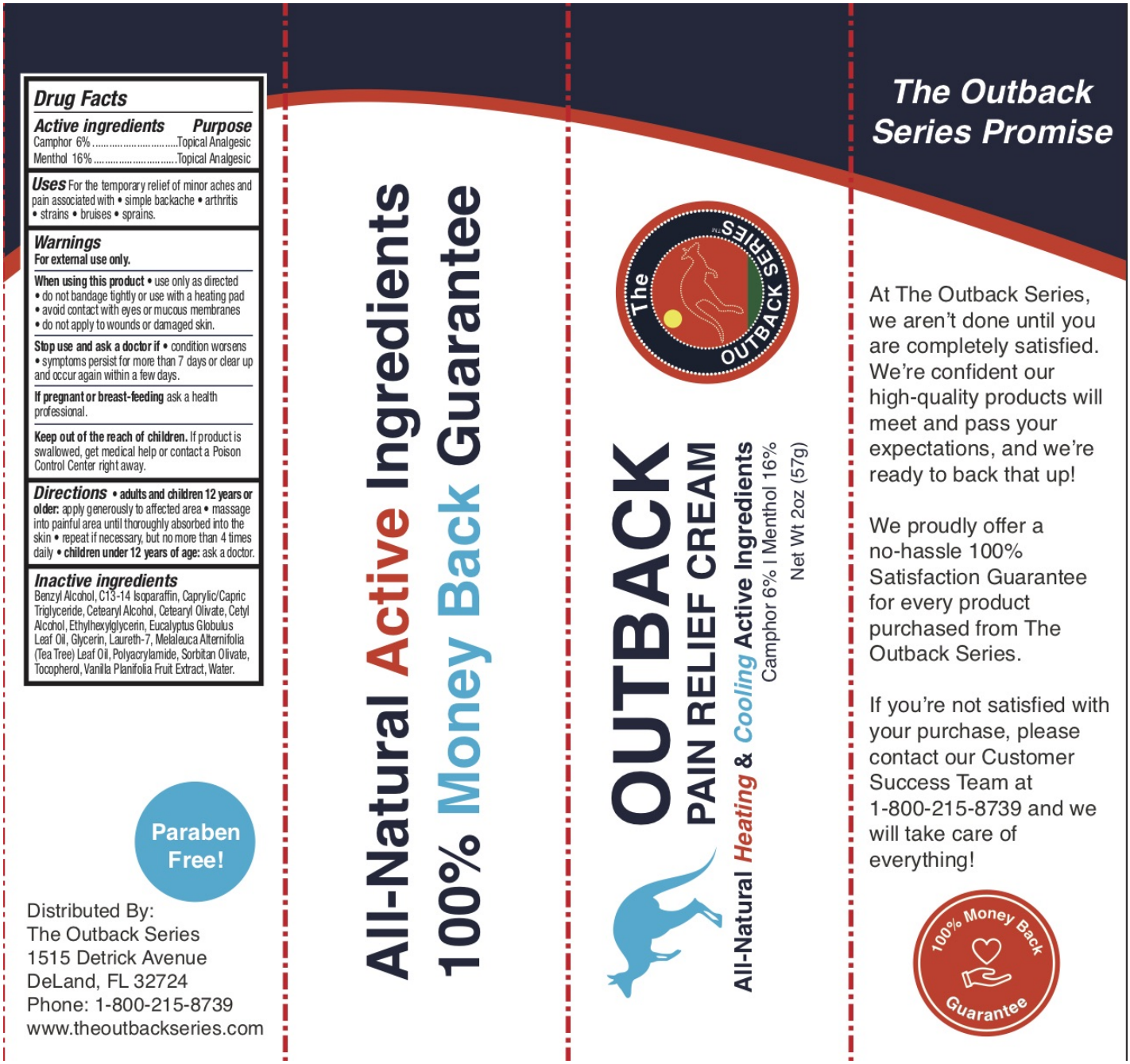
For external use only. When using this product use only as directed, do not bandage tightly or use with a heating pad, avoid contact with eyes or mucous membranes, and do not apply to wounds or damaged skin. **Stop use and ask a doctor if** condition worsens, if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding ask a health professional.

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

Adults and children 12 years of age and older apply generously to the affected area not more than 4 times daily. Children under 12 years of age: ask a doctor.

Benzyl Alcohol, C13-14 Isoparaffin, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetearyl Olivate, Cetyl Alcohol, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Glycerin, Laureth-7, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Polyacrylamide, Sorbitan Olivate, Tocopherol, Vanilla Planifolia Fruit Extract, Water.



OUTBACK PAIN RELIEF

camphor 6%, menthol 16% cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72839-987
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	6 g in 100 g

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
TEA TREE OIL (UNII: VIF565UC2G)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VANILLA BEAN (UNII: Q74T35078H)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-987-02	57 g in 1 TUBE; Type 0: Not a Combination Product	05/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/13/2021	

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(72839-987)

Revised: 1/2023 Derma Care Research Labs, LLC