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.

Drug Facts

Active ingredients **Purpose** .Topical Analgesic Camphor 6% Menthol 16%Topical Analgesic

Uses For the temporary relief of minor aches and pain associated with • simple backache • arthritis • strains • bruises • sprains.

Warnings

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 do not apply to wounds or damaged skin.

Stop use and ask a doctor if . condition worsens 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

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 generously to affected area . massage into painful area until thoroughly absorbed into the skin • repeat if necessary, but no more than 4 times daily . children under 12 years of age: ask a doctor

Inactive ingredients

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.

> Paraben Free!

1515 Detrick Avenue DeLand, FL 32724 Phone: 1-800-215-8739 www.theoutbackseries.com

Product Information

The Outback Series Promise



Cooling Active Ingredients Camphor 6% I Menthol 16%

At The Outback Series, we aren't done until you are completely satisfied. We're confident our high-quality products will meet and pass your expectations, and we're ready to back that up!

We proudly offer a no-hassle 100% Satisfaction Guarantee for every product purchased from The Outback Series.

If you're not satisfied with your purchase, please contact our Customer Success Team at 1-800-215-8739 and we will take care of everything!



Distributed By: The Outback Series

OUTBACK PAIN RELIEF

camphor 6%, menthol 16% cream

1 Todace III of Illacion								
								_

Item Code (Source) NDC:72839-987 **Product Type** HUMAN OTC DRUG

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (LINII: 5TID82A1FT) (CAMPHOR (SYNTHETIC) -	CAMPHOR	

UNII:5TJD82A1ET)

(SYNTHETIC)

6 g in 100 g

16 ~

MENTHOL 10 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)					

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		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			
final		33,13,1311			

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