ARTREX- camphor, menthol, and turpentine cream Bioved Pharmaceuticals

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.

Composition

Active Ingredients:

Camphora Officinarum (Camphor) 5 % Mentha Piperita (Menthol) 3 % Pinus Longifolia(Turpentine Oil) 10 %

Topical Analgesic

KEEP OUT OF REACH OF CHILDREN

Temporarily relieves aches and pains of muscles and joints due to arthritis, simple backache, sprains, strains, and sports injuries

- Do not apply to wound or damaged skin
- Do not bandage tightly
- Do not swallow. If swallowed call a physician or contact a poison control center immediately
- Keep away from eyes, mucous membranes, broken or irritated skin
- If skin redness or irritation develops or pain lasts more than 10 days, discontinue use and call a physician

Other Ingredients

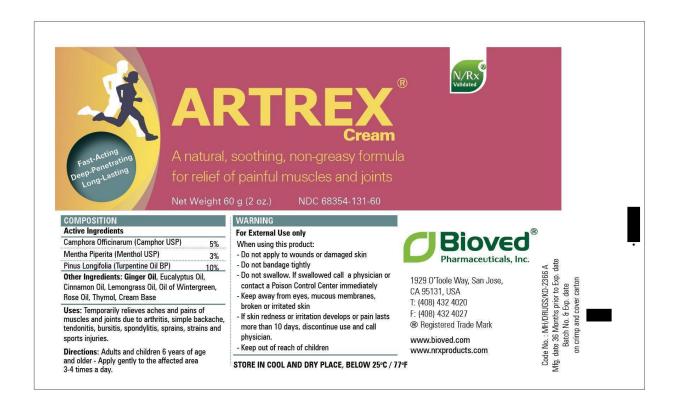
Cinnamon Oil, Eucalyptus Oil, Ginger Oil, Lemon Grass Oil, Oil of Wintergreen,

Rose Oil, Thymol, Cream Base

Adults and children 6 years of age and older

Apply to affected area 3-4 times a day

Artrex 60g Tube



ARTREX

camphor, menthol, and turpentine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68354-131
Route of Administration	TOPICAL		

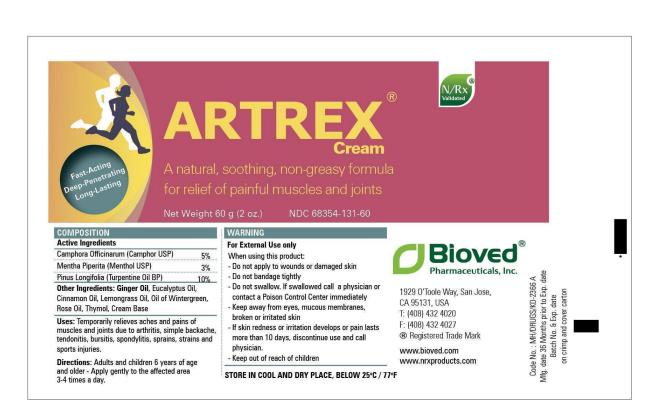
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	3 g in 60 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.8 g in 60 g		
TURPENTINE (UNII: XJ6RUH0O4G) (TURPENTINE - UNII:XJ6RUH0O4G)	TURPENTINE	6 g in 60 g		

Inactive Ingredients		
Ingredient Name	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y)		
EUCALYPTUS OIL (UNII: 2R040Ni662)		
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)		

CINNAMON OIL (UNII: E5GY4I6YCZ)	
ROSE OIL (UNII: WUB68Y35M7)	
GINGER OIL (UNII: SAS9Z1SVUK)	
THYMOL (UNII: 3J50XA376E)	

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68354-131- 60	60 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2014		
2	NDC:68354-131- 10	10 g in 1 TUBE; Type 0: Not a Combination Product	08/02/2017		



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2004	

Labeler - Bioved Pharmaceuticals (131537917)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bioved Pharmaceuticals Inc.		131537917	manufacture(68354-131)	

Revised: 9/2023 Bioved Pharmaceuticals