ARCTIC RELIEF- menthol, unspecified form gel STRATUS PHARMACEUTICALS INC

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.

ARCTIC RELIEF DRUG FACTS

Active Ingredient

Natural Menthol USP 3.5%

Purpose

Cooling Pain Reliever

Inactive Ingredients

Camphor, carbomer, FD&C blue #1, FD&C yellow #5, herbal extract, isopropyl alcohol, methyl paraben, silicon dioxide, trolamine and purified water.

Uses

Temporary relief from minor aches and pains of sore muscles & joints associated with

- arthritis
- backache
- strains
- sprains.

Warnings

FOR EXTERNAL USE ONLY.

Flammable: Keep away from excessive heat or open flame.

Ask a doctor before use if you have sensitive skin.

When Using This Product

- Avoid contact with the eyes or mucous membranes
- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams, sprays or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandage
- Wash hands after use with cool water
- Do not use with a heating pad or device.

Stop Use And Ask A Doctor If

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur.

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions

- Adults and children 2 years of age and older: Rub a thin film over affected areas not more than 4 times daily; massage not necessary.
- Children under 2 years of age: Consult physician

Other Information

Store in a cool dry place with cap closed tightly

Questions or Comments?

Call Customer Service at 800-442-7882

Distributed by:

Stratus Pharmaceuticals Inc. Miami, FL 33186

PRINCIPAL DISPLAY PANEL - 113.4 gram Tube Box

*Arctic Relief*PAIN RELIEVING GEL

NDC 58980-615-40

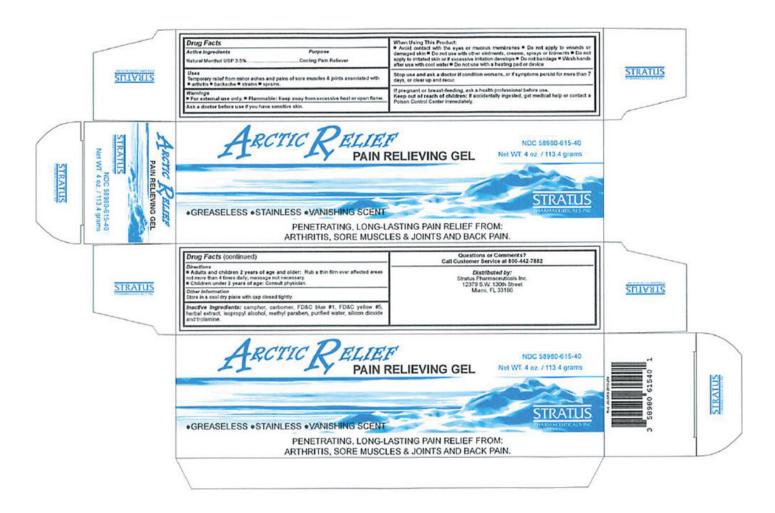
Net WT. 4 oz. / 113.4 grams

•GREASELESS •STAINLESS •VANISHING SCENT

PENETRATING, LONG-LASTING PAIN RELIEF FROM: ARTHRITIS, SORE MUSCLES & JOINTS AND BACK PAIN.

STRATUS

PHARMACEUTICALS INC



ARCTIC RELIEF

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-615
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNS PECIFIED FORM	3.969 g in 113.4 g		

Inactive Ingredients			
Ingredient Name	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)			

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-615- 40	1 in 1 BOX	09/15/2017	
1		113.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/15/2017	

Labeler - STRATUS PHARMACEUTICALS INC (789001641)

Establishment					
Name	Address	ID/FEI	Business Operations		
TARMAC PRODUCTS INC		059890491	MANUFACTURE(58980-615)		

Revised: 8/2022 STRATUS PHARMACEUTICALS INC