

**ARCTIC RELIEF- menthol, unspecified form gel**  
**STRATUS PHARMACEUTICALS INC**

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**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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58980-615
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	3.969 g in 113.4 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B404F)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)

### Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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 Drug	M017	09/15/2017	

**Labeler** - STRATUS PHARMACEUTICALS INC (789001641)

### Establishment

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

Revised: 10/2024

STRATUS PHARMACEUTICALS INC