

**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

<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 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