

**DCH COOLING PAIN RELIEF- menthol 4% gel**  
**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.*

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**DCH Cooling Pain Relief Gel, Menthol 4%**

Menthol 4%

Topical Analgesic

For the temporary relief of minor aches and pains associated with arthritis, simple backache, strains, sprains, and bruises.

**For external use only.**

**When using this product** keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin, do not bandage tightly, and do not use with heating pad.

**Stop use and ask a doctor if** condition worsens, symptoms last more than 7 days or clear and occur again within a few days.

If product is swallowed, get medical help or contact a Poison Control Center right away.

• adults and children 12 years and older, apply to affected area not more than 3 to 4 times daily. • Children under 12 years old, ask a doctor

Blue 1, carbomer, isopropyl alcohol, magnesium sulfate, sodium hydroxide, water, yellow 5.



DCH LABS

# Cooling Pain Relief Gel

Medicated

Menthol 4%

Temporary Pain Relief for Arthritis, Backache, Muscle Strains & Sprains

• Non Greasy

• Quick Drying

\* Compare to active ingredient in BioFreeze®

3 fl oz (89 mL)

## Drug Facts

### Active ingredient

Menthol 4% ..... Topical Analgesic

### Purpose

**Uses** For the temporary relief of minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

### Warnings

For external use only

#### When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water
- avoid contact with broken skin
- do not bandage tightly
- do not use with heating pad

#### Stop use and ask a doctor if

- condition worsens
- rash or irritation develops and lasts for more than 7 days or clear up and occur again within a few days

**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 to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

### Inactive ingredients

blue 1, carbomer, isopropyl alcohol, magnesium sulfate, sodium hydroxide, water, yellow 5

\* This product is not manufactured or distributed by Hygenic Intangible Property Holding Co.,® owner of the registered trademark BioFreeze®

Manufactured by:  
DermaCare Research Labs, LLC  
440 Fentress Blvd.,  
Daytona Beach, FL 32114



## DCH COOLING PAIN RELIEF

menthol 4% gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-297
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	4 g in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)				
WATER (UNII: 059QF0KO0R)				
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-297-03	89 mL in 1 TUBE; Type 0: Not a Combination Product	11/11/2022	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	11/11/2022		

**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(72839-297)

Revised: 7/2023

Derma Care Research Labs, LLC