## DCH PAIN RELIEVING- menthol 2% 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 Pain Relieving Gel, Menthol 2%

Menthol 2%

**Topical Analgesic** 

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

## For external use only.

Do not use with other topical pain relievers, with heating pad or heating devices.

When using this product do not use in or near the eyes, do not apply to wounds or damaged skin, do not bandage tightly.

**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

Ammonium hydroxide, blue 1, carbomer, copper PCA, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water.



- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

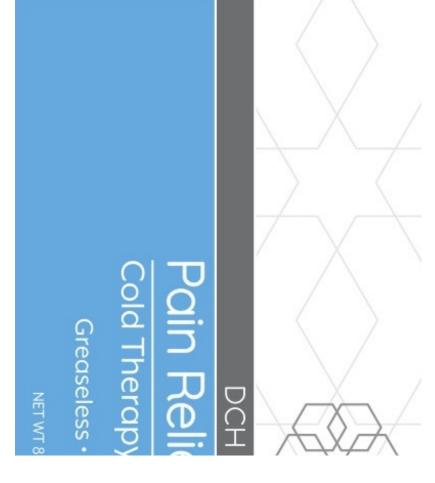
# **Directions**

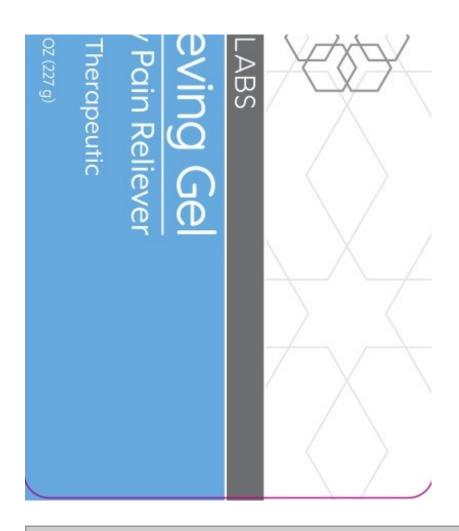
- adults and children 2 years or older: apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: ask a doctor.

**Inactive ingredients** ammonium hydroxide, blue 1, carbomer, copper pca, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water.



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





# **DCH PAIN RELIEVING**

menthol 2% gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72839-031

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthMENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)MENTHOL2 g in 100 g

# Inactive Ingredients Ingredient Name Strength AMMONIA (UNII: 5138Q19F1X) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO) COPPER PIDOLATE (UNII: 497G7G1SL1) WATER (UNII: 059QF0K00R)

WATER (UNII: 039QF0KOOK)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
THYMOL (UNII: 3J50XA376E)	
SODIUM HYDROXIDE (UNII: 55X04OC32I)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72839- 031-08	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/12/2021		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	08/12/2021				

# Labeler - Derma Care Research Labs, LLC (116817470)

# Registrant - Derma Care Research Labs, LLC (116817470)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Derma Care Research Labs, LLC		116817470	manufacture(72839-031)				

Revised: 6/2023 Derma Care Research Labs, LLC