DCH NERVE PAIN RELIEF ROLL-ON- lidocaine hcl 4%, menthol 1% 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.

DCH Nerve Pain Relief Roll-On

Lidocaine HCl 4%, Menthol 1%

Topical Analgesic

Temporarily relieves minor pain.

For external use only. Flammable--keep away from fire or flame. **Do not use** in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if the condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Adults and children 12 years and older: apply to the affected area, not more than 6 to 8 hours. Do not exceed 3 applications in a 24-hour period. Massage into painful area until thoroughly absorbed into the skin. AFTER APPLYING WASH HANDS WITH SOAP ANDWATER. Children under 12 years of age: ask a doctor.

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Alcohol Denat., Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicetyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Methylparaben, Polysorbate 60, Steareth-21, Water.

If pregnant or breastfeeding, ask a health professional before use.

Drug Facts

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Active ingredients	Purpose
Lidocaine HCI 4%	Topical anesthetic
Menthol 1%	Topical analgesic

Use temporarily relieves minor pain

Warnings

For external use only.

Flammable - keep away from fire or flame.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if • condition worsens • severe burning sensation, redness, rash or irritation develops • symptoms persist for more than 7 days or clear up and occur again within a few days • you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • adults and children over 12 years: apply thin layer to affected area

every 6 to 8 hours • do not exceed 3 applications in a 24 hour period • massage into painful area until thoroughly absorbed into skin • AFTER APPLYING WASH HANDS WITH SOAP AND WATER • children 12 years or younger: ask a doctor

Inactive ingredients acrylates/C10-30 alkyl acrylate crosspolymer, alcohol denat., aloe barbadensis leaf extract, aminomethyl propanol, C30-45 alkyl cetearyl dimethicone crosspolymer, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, dicetyl phosphate, dimethicone, disodium EDTA, ethylhexylglycerin, glyceryl stearate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isohexadecane, methylparaben, polysorbate 60, steareth-21, water



DermaCare Research Labs, LLC

440 Fentress Blvd., Daytona Beach, FL 32114



DCH LABS

Nerve Pain Relief Roll-On

Maximum Strength

Lidocaine HCl 4% - Topical Anesthetic Menthol 1% - Topical Analgesic

> Targets Multiple Nerve Pain Receptors

> > NET WT 3 OZ (85 g)



lidocaine hcl 4%, menthol 1% gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72839-014

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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g	
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g	

Inactive Ingredients Ingredient Name Strength

ISOHEXADECANE (UNII: 918X1OUF1E)

HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S

AT 1%) (UNII: 86FQE96TZ4)

STEARETH-21 (UNII: 53J3F32P58)

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER (UNII: 4ZK9VP326R)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
ALCOHOL (UNII: 3K9958V90M)	

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72839-014- 03	85 g in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2023	

ng Start Marketing End Ite Date
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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(72839-014)	

Revised: 6/2023 Derma Care Research Labs, LLC