DCH PAIN RELIEF ROLL-ON- lidocaine hcl 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.

DCH Pain Relief Roll-On

Lidocaine HCl 4%

Topical Analgesic

For the temporary relief of pain and itching.

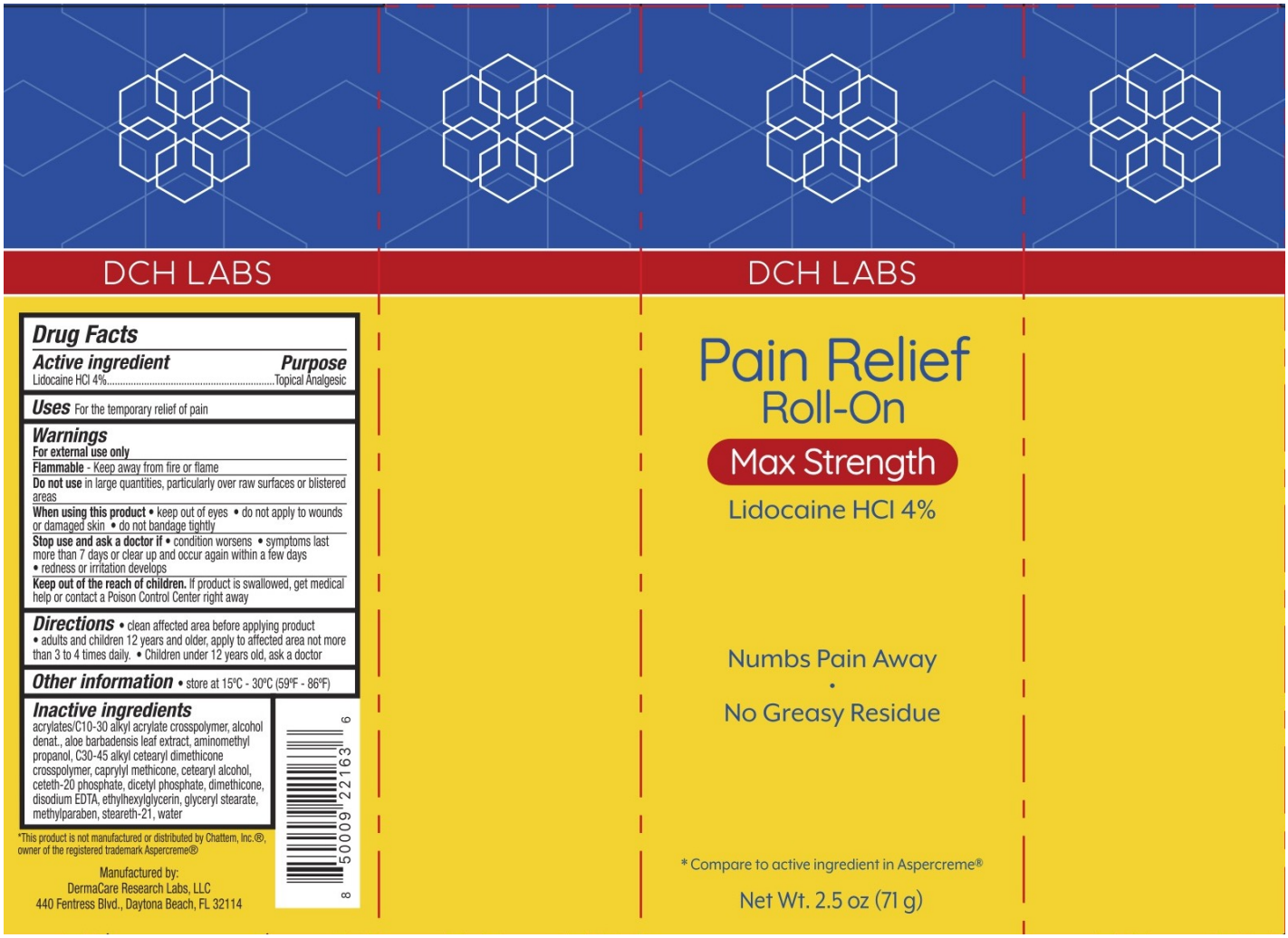
For external use only. Flammable--keep away from fire or flame. **Do not use** in large quantities, particularly over raw surfaces or blistered areas. **When using this product** keep out of eyes, do not apply to wounds or damaged skin, do not bandage tightly.

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.

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 3 to 4 times daily. Children under 12 years of age: ask a doctor.

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 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, Methylparaben, SD Alcohol 40, Steareth-21, Water.



DCH PAIN RELIEF ROLL-ON

lidocaine hcl 4% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72839-087
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
STEARETH-21 (UNII: 53J3F32P58)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-087-02	1 in 1 CARTON	04/21/2022	
1		71 g in 1 BOTTLE; 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	04/21/2022	

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(72839-087)

Revised: 6/2023 Derma Care Research Labs, LLC