

**MAXIMUM STRENGTH COLD AND HOT CVS- lidocaine hci 4% menthol 1% cream
CVS**

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.

Drug Facts

Active ingredients	Purpose
Lidocaine HCL 4%.....	Topical analgesic
Menthol 1%.....	Topical analgesic

Uses

Temporarily relieves pain and itching due to:
• sunburn • minor burns • minor cuts • scrapes • insect bites

Warnings

For external use only

Do not use • in large quantities, particularly over raw surface or blistered areas

When using this product

- avoid contact with eyes
- do not apply to wounds or damages skin
- do not bandage tightly or use with a heating pad
- use only as directed

Stop use and ask a doctor if

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

Keep out of reach of the children

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

Directions

- adults and children 12 years of age and older: spray on affected area, not more than 3 to 4 times daily
- children under 12 years of age: consult a doctor

Inactive ingredients

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 SE
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer
Isohexadecane
Methylparaben
Polysorbate 60
SD Alcohol 40
Steareth-21
Water





Drug Facts

Active ingredients

Lidocaine HCl 4%.....	Topical anesthetic
Menthol 1%.....	Topical analgesic

Purpose

Uses Temporarily relieves pain, itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites.

Warnings

For external use only.

Do not use • in large quantities, particularly over raw surfaces or blistered areas • to wound or damaged, broken, or irritated skin

When using this product • use only as directed. Read and follow all directions and warnings on this label • rare cases of serious burns have been reported with products of this type • do not bandage tightly or apply local heat (such as heating pads) to the area of use or use with a medicated patch • avoid contact with eyes and mucous membranes

Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days

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

Directions Keep carton as it contains important information. Close cap tightly between uses. **Adults and children over 12 years:** • apply to affected area 3-4 times daily • after applying, wash hands with soap and water. **Children 12 years or younger:** ask a doctor.

Inactive ingredients 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, Dicyetyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate SE, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Methylparaben, Polysorbate 60, SD Alcohol 40, Steareth-21, Water.

Questions or comments? 855-543-3784

MAXIMUM STRENGTH COLD AND HOT CVS

lidocaine hci 4% menthol 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-667
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 mL
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Ceteth-20 Phosphate (UNII: 921FTA1500)
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)
Dimethicone (UNII: 92RU3N3Y1O)
EDETATE DISODIUM (UNII: 7FLD91C86K)
Ethylhexylglycerin (UNII: 147D247K3P)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
Isohexadecane (UNII: 918X1OUF1E)
Methylparaben (UNII: A218C7H9T)
Polysorbate 60 (UNII: CAL22UVI4M)
ALCOHOL (UNII: 3K9958V90M)
Steareth-21 (UNII: 53J3F32P58)
Water (UNII: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-667-03	1 in 1 CARTON	01/30/2018	
1		80 mL 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	01/30/2018	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(69842-667) , label(69842-667)