

CVS HEALTH COLD AND HOT ROLL-ON - lidocaine, menthol cream NATURAL ESSENTIALS, INC.

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

Lidocaine HCl 4%

Menthol 1%

Purpose

Topical anesthetic

Topical analgesic

Uses

temporarily relieves minor pain

Warnings

For external use only

- Avoid contact with eyes or mucous membranes
- Do not apply to open wounds or damaged skin
- Do not bandage or use heating pad

Do not use

- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

Stop use and ask a doctor if

- Condition worsens
- severe skin irritation occurs
- Symptoms persist for more than 7 days or clear up then reoccur again within a few days

Ask a doctor before use if you

- Have sensitive skin
- Are pregnant or breastfeeding

Keep out of reach of children.

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

Directions

Rub on affected area - repeat 3 to 4 times daily

- for adults and children 12 or over
- under 12 consult doctor before use

Other information

- This product may cause allergic reaction in some individuals. Test on small area before use.

Inactive ingredients

Acrylates/C10-30 Alkyl Crosspolymer, Aloe Vera Gel 10x, Aminomethyl Propanol, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicyetyl Phosphate, Deionized Water, Dimethicone, Caprylyl Methicone, Polysilicone-11, Disodium EDTA, Ethylhexylglycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 60, Methylparaben, SDA 40-2 Alcohol, Steareth-21

Principal Display Panel - 73.9 mL Carton Label

CVS Health®

Compare to active
ingredients in IcyHot®
Lidocaine Plus Menthol*

MAXIMUM STRENGTH

Lidocaine concentration without a prescription†

Lidocaine Pain Relief Roll-On

PLUS MENTHOL

LIDOCAINE HCl 4%

MENTHOL 1%

- **Safe & effective**
- **Fast acting & long lasting**
- **Desensitizes
aggravated nerves**

† Among over the counter
topical analgesics.

Actual Bottle Size
on Side Panel

2.5 FL OZ (73.9 mL)



Principal Display Panel - 73.9 mL Container Label

CVS
Health®

MAXIMUM STRENGTH

**Lidocaine concentration
without a prescription†**

**Lidocaine
Pain Relief
Roll-On**

PLUS MENTHOL

LIDOCAINE HCl 4%

MENTHOL 1%

- Safe & effective
- Fast acting & long lasting
- Desensitizes aggravated nerves

2.5 FL OZ (73.9 mL)

<p>Drug Facts</p> <table><tr><td>Active ingredients</td><td>Purpose</td></tr><tr><td>Lidocaine HCl 4%.....</td><td>Topical anesthetic</td></tr><tr><td>Menthol 1%.....</td><td>Topical analgesic</td></tr></table> <p>Uses temporarily relieves minor pain</p> <p>Warnings</p> <p>For external use only</p> <ul style="list-style-type: none">▪ Avoid contact with eyes or mucous membranes▪ Do not apply to open wounds or damaged skin▪ Do not bandage or use heating pad <p>Do not use ▪ on large areas of the body or on cut, irritated or swollen skin ▪ on puncture wounds ▪ for more than one week without consulting a doctor</p> <p>Stop use and ask a doctor if ▪ Condition worsens ▪ severe skin irritation occurs ▪ Symptoms persist for more than 7 days or clear up then reoccur again within a few days</p> <p>Ask a doctor before use if you ▪ Have sensitive skin ▪ Are pregnant or breastfeeding</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions Rub on affected area - repeat 3 to 4 times daily ▪ for adults and children 12 or over ▪ under 12 consult doctor before use</p> <p>Other information ▪ This product may cause allergic reaction in some individuals. Test on small area before use.</p> <p>Inactive ingredients Acrylates/C10-30 Alkyl Crosspolymer, Aloe Vera Gel 10x, Aminomethyl Propanol, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicapryl Phosphate, Deionized Water, Dimethicone, Caprylyl Methicone, Polydimethylsiloxane-11, Disodium EDTA, Ethylhexylglycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 60, Methylparaben, SDA 40-2 Alcohol, Steareth-21</p>	Active ingredients	Purpose	Lidocaine HCl 4%.....	Topical anesthetic	Menthol 1%.....	Topical analgesic	<p>†Among over the counter topical analgesics.</p> <p> how2recycle.info PLASTIC BOTTLE</p> <p>Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895 © 2023 CVS/pharmacy CVS.com® 1-800-SHOP CVS V-33548</p> <p> 100% money back guaranteed. CVS.com/returnpolicy</p>	<p> CVS Health.</p> <p>MAXIMUM STRENGTH Lidocaine concentration without a prescription†</p> <p>Lidocaine Pain Relief Roll-On</p> <p>PLUS MENTHOL</p> <p>LIDOCAINE HCl 4% MENTHOL 1%</p> <ul style="list-style-type: none">• Safe & effective• Fast acting & long lasting• Desensitizes aggravated nerves <p></p> <p>2.5 FL OZ (73.9 mL)</p>
Active ingredients	Purpose							
Lidocaine HCl 4%.....	Topical anesthetic							
Menthol 1%.....	Topical analgesic							

CVS HEALTH COLD AND HOT ROLL-ON

lidocaine, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-156
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	41 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
ALCOHOL (UNII: 3K9958V90M)	
STEARETH-21 (UNII: 53J3F32P58)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-156-25	1 in 1 BOX	09/14/2018	
1		73.9 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not			

OTC monograph not final	part348	09/14/2018	
-------------------------	---------	------------	--

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-156)

Revised: 6/2023

NATURAL ESSENTIALS, INC.