

**LID O CREME ROLL ON- lidocaine hcl, menthol cream**  
**Pharma Natural, 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.*

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**LID O CREME**

**DRUG FACTS**

**Active ingredients and Purpose**

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<i>Active ingredients</i>	<i>Purpose</i>
Lidocaine HCL 4%.....	Topical analgesic
Menthol 1%.....	Topical analgesic

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***Use***

For the temporary relief of pain.

***Warnings***

**For external use only.** Avoid contact with the eyes.

**Do not use**

in large quantities, particularly over raw surfaces, or blistered areas.

**Stop use and ask a doctor if**

condition worsens, or if 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 reach of children.**

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

***Directions***

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

***Other information***

- store in a cool dry place between (59-86°F)15-30°C
- don't use if seal over cap is broken, torn, or missing

***Inactive ingredients***

aloe vera leaf, alpha-tocopherol, arnica montana flower, caprylhydroxamic acid, caprylyl glycol, cyclomethicone 5, dimethicone, dimethyl sulfone, glycerin, glyceryl monostearate, glycol stearate, methylpropanediol, PEG-100 stearate, PEG/PPG-18/18-dimethicone, phenoxyethanol, sodium lauryl sulfate, sodium polyacrylate, stearyl alcohol, sweet almond oil, trideceth-6, water

***Questions or comments?***

+1-305-231-8977 (M-F) 9 A.M. - 5 P.M. EST or [www.pharmanatural.com](http://www.pharmanatural.com)

**Manufactured & Distributed by:**

**Pharma Natural, Inc.**

Hialeah, FL 33016

**Principal Display Panel**

PAIN RELIEVING

Pharma Natural

Natural Health Solutions

Lid O Creme

Maximum Strength

Topical Analgesic Cream

Roll-On

LIDOCAINE HCL 4%

MENTHOL 1%

2.5 oz. (71 g)



## LID O CREME ROLL ON

lidocaine hcl, menthol cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63788-111
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

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
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
TRIDECETH-6 (UNII: 3T5PCR2H0C)
WATER (UNII: 059QF0KO0R)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
DIMETHICONE (UNII: 92RU3N3Y1O)
GLYCOL STEARATE (UNII: 0324G66D0E)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
ALMOND OIL (UNII: 66YXD4DKO9)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PEG-100 STEARATE (UNII: YD01N1999R)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63788-111-25	71 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	06/01/2018	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2018	

**Labeler** - Pharma Natural, Inc. (138059287)