

## **SERA RELIEF ULTIMATE RAPID SOOTHING CREME- lidocaine hcl cream**

**Sera Labs, Inc., The**

*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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## **SERA RELIEF ULTIMATE RAPID SOOTHING CREME**

### **Drug Facts**

#### **Active Ingredients**

Lidocaine 4%

#### **Purpose**

Topical Analgesic

**Uses:** Temporarily relief from minor pain associated with: • arthritis • bruises • simple backache • muscle strains • cramps • sprains

**Warning:** For external use only

**Flammable:** Keep away from excessive heat or open flame

**When using this product:** Avoid contact with eyes or mucous membrane. Do not apply to wounds, damaged, blistered or irritated skin. Do not use with other ointments, creams, sprays or liniments. Do not bandage. Wash hands after use with cool water. Do not use with heating pad or device.

**Ask a doctor** before use if you have sensitive skin. Stop use if condition worsens or persists for more than 7 days.

**If pregnant or breast feeding:** ask doctor before using

**Keep out of reach of children:** if accidentally ingested get medical help or contact a Poison Control Center immediately

**Recommended Use:** Adults, with container rub a thin film over affected areas, not more than 3-4 times in 24 hour period, massage is not necessary.

**Other information:** store in cool dry place

**Inactive Ingredients:** Allantoin, Caprylic/Capric Triglyceride, Capsicum Annuum Fruit powder, Calcium Disodium EDTA, Cannabis Sativa (Aerial) Extract Oil, DL-Alpha Tocopheryl Acetate, Ethyl Alcohol, Ethylhexylglycerin, Ethylhexyl Stearate, Glycerin, Phenoxyethanol, Polysorbate 80, Propanediol, Propylene Glycol, Purified Water, Simethicone, Sodium Polyacrylate, Trideceth-6, Vitis Vinifera (Grape) seed Oil, Xanthan Gum, Beta – Caryophyllene

### **Feet & Legs**

**4% LIDOCAINE**

WITH CBD 300mg

## Packaging



The packaging is a vertical rectangular box with a teal top and bottom section and a white middle section. The top teal section features the brand name 'Sera Relief' in white, with 'TM' to the right, and a stylized purple and blue leaf with a drop of liquid. Below this, the text 'Feet & Legs' is in teal, followed by 'ULTIMATE Rapid Soothing Creme' in a mix of teal and black. '4% LIDOCAINE' is written in large teal letters. A white box with a black border contains the text 'WITH CBD 300mg'. The bottom teal section contains the text 'CONVENIENT NO-MESS ROLL ON' and '73 ml - 2.5 fl oz'.

**Sera Relief™**

Feet & Legs

**ULTIMATE**  
Rapid  
Soothing  
Creme

**4% LIDOCAINE**

WITH  
**CBD**  
300mg

CONVENIENT  
NO-MESS ROLL ON

73 ml - 2.5 fl oz

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73385-104-60

**SERA RELIEF ULTIMATE RAPID SOOTHING CREME**

lidocaine hcl cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73385-104
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PAPRIKA (UNII: X72Z47861V)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CANNABIS SATIVA SUBSP. SATIVA FLOWERING TOP (UNII: 8X454SZ22D)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPANEDIOL (UNII: 5965N8W85T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARYOPHYLLENE (UNII: BHW853AU9H)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73385-104-60	73 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/04/2019	

**Labeler** - Sera Labs, Inc., The (116914405)

Revised: 10/2019

Sera Labs, Inc., The