

**HEMPORRHOID- lidocaine hcl cream**  
**Renu Laboratories, 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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**HEMPORRHOID CREAM**

Hemorrhoidal Cream

Lidocaine HCl 5%

Topical Anesthetic

**Uses**

For the temporary relief of

- Pain
- Itching
- Burning associated with inflamed hemorrhoidal tissues

For external use only

**When using this product**

- Keep out of eyes. Rinse with water to remove. Do not use in large quantities, particularly over raw surfaces or blistered areas.

**Stop use and ask a doctor if** conditions worsen, or, if symptoms persist for more than 7 days, or clear up and occur again within a few days. Discontinue use of this product and consult a doctor.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

**If pregnant or breast-feeding,** ask a health professional before use.

**Directions:**

**Adults and children 2 years of age and older:** apply to affected area not more than 3 - 4 times daily.

**Children under 2 years of age:** Consult a doctor.

**Other information:** Store between 58 - 87° F

Protect from freezing, direct heat or sunlight.




**Questions?** [www.marswellness.com](http://www.marswellness.com)

Mars Wellness

Lakewood, NJ 08701

INGREDIENTS: Capryl Glycol, Caprylic / Capric Triglyceride, Cetearyl Alcohol, Deionized Water, Emulsifying Wax NF, Ethylhexylglycerin, Glycerin, Hemp Extract with proprietary Terpene blend: (Beta Caryophyllene, Humulene, Limonene, Myrcene, Linalool, Nerolidol, Beta Pinene, Alpha Pinene, Eucalyptol), Hexylene Glycol, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Stearic Acid, Tetrasodium EDTA, Tocopherol.

## HEMPORRHOID TUBE ART

<p>Maximum Strength! 5% Lidocaine</p> <p><b>HEMPORRHOID</b></p> <p>Hemorrhoidal Cream</p> <p>Enhanced with Hemp Extract</p> <p>Net Wt. 1fl. oz. 30ML</p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Lidocaine HCl 5%.....</td> <td>Topical Anesthetic</td> </tr> <tr> <td colspan="2"><b>Uses</b> For the temporary relief of • Pain [itching • Burning associated with inflamed hemorrhoidal tissues</td> </tr> <tr> <td colspan="2"><b>Warnings</b> For External use only</td> </tr> <tr> <td colspan="2"><b>When using this product</b> • Keep out of eyes. Rinse with water to remove. Do not use in large quantities, particularly over raw surfaces or blistered areas.</td> </tr> <tr> <td colspan="2"><b>Stop use and ask a doctor</b> if conditions worsen, or, if symptoms persist for more than 7 days, or clear up and occur again within a few days, discontinue use of this product and consult a doctor.</td> </tr> <tr> <td colspan="2"><b>Keep out of reach of children.</b> if swallowed, get medical help or contact a poison control center right away <b>If pregnant or breast-feeding,</b> ask a health professional before use.</td> </tr> <tr> <td colspan="2"><b>Directions:</b> Adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily. Children under 2 years of age: Consult a doctor.</td> </tr> <tr> <td colspan="2"><b>Other information:</b> Store between 58°-87°F Protect from freezing, direct heat or sunlight</td> </tr> <tr> <td colspan="2"><b>INGREDIENTS:</b> Capryl Glycol, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Deionized Water, Emulsifying Wax NF, Ethylhexylglycerin, Glycerin, Hemp Extract with proprietary Terpene blend (Beta Caryophyllene, Humulene, Limonene, Myrcene, Linalool, Nerolidol, Beta Pinene, Alpha Pinene, Eucalyptol), Hexylene Glycol, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Stearic Acid, Tetrasodium EDTA, Tocopherol.</td> </tr> <tr> <td colspan="2">Questions? <a href="http://www.marswellness.com">www.marswellness.com</a></td> </tr> <tr> <td>Mars Wellness Lakewood NJ 08701</td> <td></td> </tr> </table>	Active Ingredients	Purpose	Lidocaine HCl 5%.....	Topical Anesthetic	<b>Uses</b> For the temporary relief of • Pain [itching • Burning associated with inflamed hemorrhoidal tissues		<b>Warnings</b> For External use only		<b>When using this product</b> • Keep out of eyes. Rinse with water to remove. Do not use in large quantities, particularly over raw surfaces or blistered areas.		<b>Stop use and ask a doctor</b> if conditions worsen, or, if symptoms persist for more than 7 days, or clear up and occur again within a few days, discontinue use of this product and consult a doctor.		<b>Keep out of reach of children.</b> if swallowed, get medical help or contact a poison control center right away <b>If pregnant or breast-feeding,</b> ask a health professional before use.		<b>Directions:</b> Adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily. Children under 2 years of age: Consult a doctor.		<b>Other information:</b> Store between 58°-87°F Protect from freezing, direct heat or sunlight		<b>INGREDIENTS:</b> Capryl Glycol, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Deionized Water, Emulsifying Wax NF, Ethylhexylglycerin, Glycerin, Hemp Extract with proprietary Terpene blend (Beta Caryophyllene, Humulene, Limonene, Myrcene, Linalool, Nerolidol, Beta Pinene, Alpha Pinene, Eucalyptol), Hexylene Glycol, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Stearic Acid, Tetrasodium EDTA, Tocopherol.		Questions? <a href="http://www.marswellness.com">www.marswellness.com</a>		Mars Wellness Lakewood NJ 08701	
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### HEMPORRHOID

lidocaine hcl cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76348-590
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	1.4 g in 28 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARYOPHYLLENE</b> (UNII: BHW853AU9H)	
<b>.BETA.-PINENE</b> (UNII: 4MS8VHZ1HJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>HUMULENE</b> (UNII: 54W56MD2WD)	
<b>MYRCENE</b> (UNII: 3M39CZS25B)	
<b>LINALOOL, (+)-</b> (UNII: F4VNO44C09)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>CANNABIDIOL</b> (UNII: 19GBJ60SN5)	
<b>EUCALYPTOL</b> (UNII: RV6J6604TK)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>.ALPHA.-PINENE</b> (UNII: JPF3YI7O34)	
<b>NEROLIDOL</b> (UNII: QR6IP857S6)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-590-02	1 in 1 BOX	11/23/2020	
1	NDC:76348-590-01	28 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/23/2020	

**Labeler** - Renu Laboratories, Inc. (945739449)

## Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-590)

Revised: 1/2022

Renu Laboratories, Inc.