

## **LIDOCAINE 5 PERCENT- lidocaine cream**

**Alexso, 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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### **Lidocaine 5\_Percent Cream**

## **LIDOCAINE - Lidocaine 5% anorectal cream**

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### **Lidocaine 5% Anorectal Cream**

#### **Drug Facts**

##### **Active ingredient**

Lidocaine 5% w/w

##### **Purpose**

Topical anesthetic

##### **Uses**

For the temporary relief of local pain, soreness, burning, itching or discomfort associated with anorectal disorders.

##### **Warnings**

**For external use only.**

##### **When using this product**

- avoid contact with eyes
- do not exceed recommended daily dosage unless directed by a physician
- do not put this product into the rectum by using fingers or any mechanical device or applicator
- in case of bleeding, consult a physician promptly

##### **Stop use and ask a physician if**

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase
- symptoms clear up and return within a few days
- if pregnant or breastfeeding

##### **Keep out of reach of children.**

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

**Directions**

When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.

**Adults and children 12 years and older:** Apply externally to the affected area up to 6 times a day.

**Children under 12 years of age:** Consult a physician.

**Other information**

- May be applied under occlusive dressing.
- Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

**Inactive ingredients**

Aloe Barbados Leaf (Aloe Vera Juice), Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cannabis Sativus (Hemp) Seed Oil, Ethylhexylglycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Extract, Helianthus Annuus (Sunflower) Oil, Ilex Paraguariensis (Yerba Mate) Extract, C13-14 Isoparaffin, Isopropyl Myristate, Laureth-7, Magnesium Sulfate, Phenoxyethanol, Polyacrylamide, Stearic Acid.

**PRINCIPAL DISPLAY PANEL****Lidocaine 5% Cream**

NDC 50488-6265-1

☐ **Lidocaine 5%**

Anorectal Cream

Topical Anesthetic

**50 grams**

Manufactured for:

Alexso, Inc.

Los Angeles, CA 90064

NDC: 50488-6265-1

**Lidocaine 5%**  
Topical Anesthetic Anorectal Cream

50 gram

Rev.: 06/20

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**Drug Facts (continued)**

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Questions? 1-888-495-6078

Manufactured for: Alexso, Inc.  
Los Angeles, CA 90064



**LIDOCAINE 5 PERCENT**

lidocaine cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50488-6265
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>MAGNESIUM SULFATE, UNSPECIFIED</b> (UNII: DE08037SAB)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>POLYACRYLAMIDE (10000 MW)</b> (UNII: E2KR9C9V2I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-6265-1	1 in 1 CARTON	07/01/2020	
1		50 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	07/01/2020	

**Labeler** - Alexso, Inc (963338061)

Revised: 7/2020

Alexso, Inc