

**LEADER- lidocaine hcl cream**  
**Cardinal Health**

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**Leader Lidocaine HCL 4% Cream**

***Active ingredient***

Lidocaine HCl 4%

***Purpose***

Topical analgesic

***Uses***

temporarily relieves pain and itching due to:

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- minor skin irritations

***Warnings***

**For external use only**

**Do not use** in large quantities, particularly over raw surfaces or blistered areas

**When using this product** do not get into eyes

**Stop use and ask a doctor if**

- condition gets worse
- symptoms last for more than 7 days
- symptoms clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- adults and children 2 years and over: apply to affected area not more than 3 to 4 times daily
- children under 2 years: ask a doctor

***Other information***

store between 20 °C and 25 °C (68 °F and 77 °F)

### ***Inactive ingredients***

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis (aloe vera) leaf juice, aminomethyl propanol, C30-45 alkyl cetearyl dimethicone crosspolymer, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, dicetyl phosphate, dimethicone, edetate disodium, ethylhexylglycerin, glyceryl monostearate, methylparaben, purified water, SD alcohol 40, steareth-21

### **Principal display panel**



Leader

NDC 70000-0098-1

Maximum Strength

Lidocaine

Pain Relief

Cream

Lidocaine HCl 4% Topical Analgesic

Non Greasy

Compare to aspercreme lidocaine cream

active ingredient

100% Money Back Guarantee

Net wt 2.7 oz (76.5g)



		SGS Rosemont 5500 Pearl Street, Suite 200 Rosemont, IL 60018 (712) 219-4230	SGS Job Number: <b>6364504</b>	INITIALS <b>AC</b>	DATE <b>06.24.21</b>														
		CIN Number: 5715982      Brand: LEADER Component Code: 5715982-Pre-printed Carton Product Name: Max Strength Lidocaine Pain Relief Cream 2.7oz File Name: 6364504_CAR_LDR_Max Strength Lidocaine Pain Relief Cream 2.7oz Carton_WAL_TP_26_5715982_V2.ai Die Dimensions: 10" x 7.986" Packaging Type: Pre-printed Carton	<table border="1"> <tr> <td>1</td> <td>2</td> <td>3</td> <td>4</td> <td>5</td> </tr> <tr> <td>PMS 1091</td> <td>PMS 200</td> <td>PMS 2325</td> <td>PROCESS BLACK</td> <td>VARNISH</td> </tr> <tr> <td colspan="5">DIELINE</td> </tr> </table>	1	2	3	4	5	PMS 1091	PMS 200	PMS 2325	PROCESS BLACK	VARNISH	DIELINE					Limitation of Liability: The supplied materials should be thoroughly inspected immediately upon receipt by the recipient for all content, placement and copy accuracy. It is also the responsibility of the recipient printer to examine and proofread all supplied materials before producing image carriers and printing final product. Should the supplied materials be found to be incorrect, please contact an SGS representative immediately. The liability of SGS shall be limited to correcting its own product. SGS will not be responsible for any loss or damage including but not limited to the cost of product, print, image carriers, press delays, or other ancillary cost.
1	2	3	4	5															
PMS 1091	PMS 200	PMS 2325	PROCESS BLACK	VARNISH															
DIELINE																			

**LEADER**  
lidocaine hcl cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0098
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE -	LIDOCAINE HYDROCHLORIDE	4 g

UNII:98PI200987) ANHYDROUS in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>DIHEXADECYL PHOSPHATE</b> (UNII: 2V6E5WN99N)	
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>CETETH-20 PHOSPHATE</b> (UNII: 921FTA1500)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0098-1	1 in 1 CARTON	10/18/2021	
1		76.5 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/18/2021	

**Labeler** - Cardinal Health (063997360)

**Registrant** - Weeks & Leo Company Inc (005290028)

**Establishment**

Name	Address	ID/FEI	Business Operations
Weeks & Leo Company Inc		005290028	manufacture(70000-0098)