

LEADER- lidocaine hcl cream
Cardinal Health

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.

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 (412) 219-0230	SGS Job Number: 6364504	INITIALS AC	DATE 06.24.21														
CIN Number: 5715982 Brand: LEADER Component Code: 5715982-Pre-printed Carton Product Name: Max Strength Lidocaine Pain Relief Cream 2.7oz File Name: 6364504_CAH_LDR_MSL_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 2225</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 2225	PROCESS BLACK	VARNISH	DIELINE							
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LEADER
lidocaine hcl cream

Product Information

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

Active Ingredient/Active Moiety

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

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

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 not final	part348	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)