## 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.

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#### Leader Lidocaine HCL 4% Cream

## Active ingredient

Lidocaine HCL4%

## **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

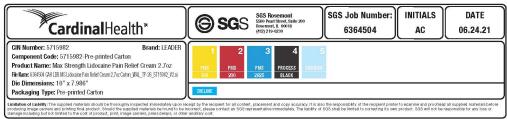
Compare to aspercreme lidocaine cream

active ingredient

100% Money Back Guarantee

Net wt 2.7 oz (76.5g)





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LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)

LIDOCAINE HYDROCHLORIDE ANHYDROUS

4 g in 100 g

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)				
<b>STEARETH-21</b> (UNII: 53J3F32P58)				
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)				
ALCOHOL (UNII: 3K9958V90M)				
METHYLPARABEN (UNII: A2I8C7HI9T)				

ı	Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:70000- 0098-1	1 in 1 CARTON	10/18/2021			
:	ı	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	<b>Business Operations</b>			
Weeks & Leo Company Inc		005290028	manufacture(70000-0098)			

Revised: 10/2021 Cardinal Health