

LEADER LIDOCAINE- lidocaine hcl liquid
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% Roll On

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

Flammable •Keep away from fire or flame

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

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

Directions

- adults and children 12 years and over: apply to affected area not more than 3 to 4 times daily
- children under 12 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

Questions or comments?

call **515-276-1586**

Principal display panel



Leader

NDC 70000-0099-1

Maximum Strength

Lidocaine

Pain Relief

Liquid
Lidocaine HCl, 4% Topical Analgesic
No Mess
Applicator
Compare to
Aspercreme
Lidocaine liquid
active ingredient
100% Money Back Guarantee
2.5 Fl oz (73 mL)

LEADER LIDOCAINE			
lidocaine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0099
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
CETETH-20 PHOSPHATE (UNII: 921FTA1500)			
STEARETH-21 (UNII: 53J3F32P58)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
DIHEXADECYL PHOSPHATE (UNII: 2V6E5VN99N)			
DIMETHICONE 350 (UNII: 2Y53S6ATLU)			
ALCOHOL (UNII: 3K9958V90M)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0099-1	1 in 1 CARTON	10/20/2021	
1		73 mL 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	10/20/2021	

Labeler - CARDINAL HEALTH (063997360)**Registrant** - Weeks & Leo Co., Inc. (005290028)**Establishment**

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(70000-0099)

Revised: 1/2022

CARDINAL HEALTH